OPTN/UNOS Membership and Professional Standards Committee
Report to the Board of Directors
June 21-22, 2010
Richmond, Virginia

Summary

I. Action Items for Board Consideration

- The Board of Directors is asked to approve the following center-specific actions. (Item 1, Page 5):
  - Fully approve ten new programs in existing transplant centers (includes living donor);
  - Conditionally approve (12 months) one transplant center to perform living donor liver transplants in an existing liver transplant program;
  - Approve one new independent laboratory;
  - Approve one new organ procurement organization;
  - Approve one new individual for a two-year term of membership;
  - Renew terms for sixteen non-institutional members; and
  - Approve changes in program status:
    - Approve nine programs to reactivate.
    - Fully approve four programs formerly under conditional status.
    - Approve a 12-month extension to the conditional status of one existing liver transplant program to perform living donor liver transplants.
    - Fully approve one kidney transplant program performing living donor kidney transplants that was previously granted an exception for compliance with Policy 12.6.
- Change to Mailing Requirement in Bylaws: The Board of Directors is asked to approve modifications to the bylaws that currently limit delivery options of certain member communications to services provided by United States Postal Service. The modifications would allow more flexibility for different methods of overnight delivery or communication by secure email. (Item 2, Pages 5-6).

II. Other Significant Items

- Annual Committee Goals: During its December and March meetings, the Committee was presented with the goals that had been approved for the year and the progress made on those goals that were already in process. (Item 3, Page 6).

- Program-Related Actions and Personnel Changes: The Committee reviewed 85 and approved 83 personnel change applications during the December meeting. The Committee was also notified that three programs inactivated, and five members/ programs withdrew from membership. The Committee was also notified of one newly registered intestinal transplant program, as well as three programs whose approval status changed from full to conditional approval. During the March meeting, the Committee reviewed 80 and approved 74 personnel change applications. The Committee was also notified that four programs inactivated, six members/programs withdrew from membership, and three programs' approval status changed from full to conditional approval. (Item 4, Page 6).

- Due Process Proceedings: During the December meeting, the Committee conducted seven interviews with member transplant centers and organ procurement organizations. During the March meeting, it conducted four additional interviews and a hearing. (Item 5, Page 7).

- Update on Enforcement of Mandatory Donation after Cardiac Death (DCD) protocols: During the January meeting, the Committee received an update on the last transplant hospital that was non-compliant with submitting a certification statement attesting that they have and employ a mandatory DCD organ recovery protocol. This hospital adopted the required mandatory DCD policy and sent its certification statement to the MPSC on 3/22/2010. (Item 6, Page 7).

- Living Donor Related Bylaws: The Committee was updated on the plans to review the bylaws related to living donor transplantation. A joint work group comprised of members from the MPSC, Living Donor Committee, Pediatric Transplantation Committee, Kidney Transplantation Committee, and the Liver and Intestinal Organ Transplantation Committee was formed to discuss this issue. (Item 7, Page 7).

- Update of Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data): As required in Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data), transplant programs must report all instances of live donor deaths and failure of the live donor's native organ function within 72 hours after the program becomes aware of the live donor death or failure of the live donors' native organ function. The Committee reviewed four reported instances in December, three in January, and three in March. (Item 8, Page 7).

- OPO Performance Metrics: The Committee was updated on the work of the OPO Performance Metrics Work Group, which comprises members of the OPO Committee and the MPSC. The Work Group is tasked with developing performance metrics to maximize the utilization of organs. There will be an educational conference for the OPO community on May 27, 2010, in Chicago. (Item 9, Page 8).

- Modified Flagging Methodology: During the December meeting, UNOS staff presented a retrospective analysis of the modified flagging criteria proposed by the SRTR. In summary, the analysis showed that using the proposed method, the MPSC would flag fewer programs overall, while flagging more medium and high volume programs. The analysis also showed that the proposed method would flag >80% of the programs considered "true positives" using the current flagging method and would flag fewer of the current false positives. The MPSC recommended conducting a simulation to determine an appropriate flagging methodology to capture the small volume programs that might be missed if the modified flag is adopted as the only flagging mechanism for one-year post-transplant outcomes. (Item 10, Page 8).

- Composite Pre-Transplant Metric (CPM): The MPSC was apprised of the CPM Work Group's progress. To facilitate the work of the work group and identify potential flagging thresholds, an in-person meeting of the work group will occur on April 28, 2010, in Chicago. (Item 11, Pages 8-9).

- Qualifications for Directors, Liver Transplant Program Anesthesiology: The Committee discussed a memorandum from the American Society of Anesthesiology, which has

suggested qualifications for the directors of liver transplant anesthesia. At the Committee's request, a subcommittee developed a draft proposal for the full Committee to review during its March meeting. It noted its appreciation for the work done by the ASA and agreed that it should seek input from the other organ specific Committees to determine if the proposal should be expanded beyond liver programs. (Item 13, Page 9).

- Data Coordination Responsibilities and Guidelines: During the December meeting the Committee reviewed responses from the OPO, Histocompatibility, Transplant Administrators, and Transplant Coordinators Committees on the necessity for codifying the responsibilities and expectations for primary data coordinators in the bylaws. Additionally, the MPSC was made aware of UNOS staff projects relating to data submission. (Item 14, Page 9).

- Proposal to Add Valuable Consideration Disclosure to Bylaws: Under this proposal, distributed for public comment in November 2009, transplant centers would be required to document that potential living organ donors have been informed that the sale or purchase of human organs (kidney, liver, heart, lung, pancreas, and any other human organ) is a federal crime. The MPSC reviewed this proposal during its December meeting and agreed to support it. (Item 17, Page 10).

- Notification of Changes in Key Personnel: The Committee discussed the timeliness of notifications and submission of applications for changes in key personnel in transplant programs as it pertains to the bylaw changes that were made last year. Discussion centered on the process that should be followed when members fail to comply. (Item 20, Page 11).

- Patterns and Trends of Member Compliance and MPSC Actions: During the December and March meetings, UNOS staff presented a summary of trends in member center site survey results and allocation issues. Staff presented summaries of policy violations found on site surveys and of types of allocation deviations found during allocation analysis and other reports to UNOS, as well as Committee actions on past potential policy violations. Staff analyzed data by region and method of reporting. Staff presented a possible path for future trend analysis to the Committee. (Item 23, Page 12).

- Establishment of Processes to Enforce Standards for Individuals Procuring Deceased Donor Organs for Transplantation: The Committee reviewed the proposal from the ASTS entitled "Recommendations for Standards for Individuals Procuring Deceased Donor Organs for Transplantation" but did not reach a consensus on a path forward. (Item 24, Pages 12-14).

- Living Donor Pilot Program: The Committee was briefed on the DEQ pilot survey of five living kidney donor programs conducted in February and March 2010. UNOS staff used a newly developed survey plan including review of the programs' living donor protocols and compliance with the same, review of data, staff interviews, and tracer methodology to verify awareness of program protocols. (Item 26, Page 14).

- Voting Status of Hospital-Based OPOs and Laboratories: During the December meeting, the Committee discussed a request that hospital based OPOs be granted OPTN voting rights as a part of their membership under the parent transplant center. A work group previously tasked with considering this issue reported on the results of its first meeting. The Committee asked the work group to develop a cost assessment for changing the voting status. (Item 27, Pages 14-15).

- UNOS Actions: The Committee members agreed that actions regarding Bylaws and Policy, and program-specific decisions made during the OPTN session would be accepted as UNOS actions. (Item 28, Page 15).

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Charles E. Alexander, RN, BSN, MBA, CPTC, Chair
David C. Mulligan, M.D., Vice Chair

I. Regular Committee Meetings. The Membership and Professional Standards Committee (MPSC) met on December 8-10, 2009, and March 23-25, 2010, in Chicago, Illinois; and on January 25, and April 28, 2010, by conference call and Microsoft Live Meeting. The Committee's deliberations and recommendations are provided below.

1. Membership Application Issues: The Committee is charged with determining that member clinical transplant programs, organ procurement agencies, histocompatibility laboratories, and non-institutional members meet and remain in compliance with the Criteria for Institutional Membership and transplant program approval. During each meeting, it considers actions regarding the status of current members and new applicants. The Committee took the actions reported below during its December, January, and March meetings.

   The Committee recommends that the Board of Directors approve one new histocompatibility laboratory, one new organ procurement organization and eleven new programs (including living donor) in existing member centers. It also recommended approval for new and continued membership for existing non-institutional members.

   During the December 2009 meeting, the Committee reviewed eight transplant programs that had previously voluntarily inactivated and approved reinstatement of the programs' active status. The Committee reviewed and approved requests from four transplant programs for changes in status from conditional approval to full approval. The Committee also reviewed and approved a 12-month extension to the conditional approval status of a liver transplant program to perform living donor liver transplants.

   During the March meeting, the Committee reviewed one transplant program that had previously voluntarily inactivated and approved reinstatement of the program's active status. The Committee also reviewed and approved a request for full approval for a kidney transplant program to perform living donor kidney transplants. This program had previously operated under an exception for compliance with Policy 12.6.

2. Proposal for Revision of OPTN and UNOS Bylaws Regarding Mailing Requirements: The Committee reviewed a staff proposal to revise the OPTN and UNOS Bylaws to broaden the language that describes how correspondence required by the bylaws should be delivered between the OPTN and members and members and patients. Currently, the bylaws limit delivery of many communications to specific services that are provided by the United States Postal Service (USPS). The proposed language would accommodate modern delivery methods that meet the needs for security and tracking and that also provide faster and, often, less costly service than the currently required USPS services. In addition, the more general proposed language allows for use of future innovations in delivery methods without an additional revision to the bylaws. The proposed revisions were not distributed for public comment because the proposed revisions would not affect allocation of organs or have membership services implications. The following proposed language would replace references to USPS services wherever it appears in the bylaws.

The Committee agreed to support the proposal as written 23 For, 0 Against, 0 Abstentions.

> ** **RESOLVED, that Article I, Article II, Article X, Appendix A and Appendix B of the OPTN Bylaws and Article I, Article II, Article X, Appendix A, and Appendix B, II, C of the UNOS Bylaws shall be amended as set forth in Exhibit A, effective pending notice to the membership.**

A copy of the Briefing Paper, which addresses the details of the proposal, is attached as Exhibit A of this report.

3. Overview of Annual Committee Goals: During each of the meetings, updates were provided to the Committee on the goals that were approved for the 2009-2010 as well the goals that were tasked to the Committee in previous years. A list of the goals is provided below and each is addressed in more detail later in this report.

    - Review bylaws pertaining to program certification for currency and relevance. (Items 7, 13, 14, and 20).
    - Review the living donor program requirements for currency and relevance and to determine if the original goal of the requirements (to improve the process of living donation and transplantation through standardized levels of experience and quality) is being met. (Items 7 and 8)
        - Examination of program requirements regarding adult and pediatric living donor recoveries
        - Separation of care for living donors.
        - Consideration of living donor program performance metric(s).
        - Implement, monitor, and oversee compliance with bylaws and policies pertaining to programs that do living donor transplants.
    - Develop and consider use of pre-transplant program performance metrics for flagging. (Item 11).
    - Consider processes for reviewing programs with evolving problems, including post-transplant or personnel problems. (Item 10).
    - Participate in the bylaws rewrite project. (Items 7, 9, 10, 11, 13, 14, 24, and 27).
    - Clarification of member responsibilities for complying with bylaws and policies [such as conflicts of interest regarding declaration of death and organ procurement]. (Item 6).
    - OPO Metrics: Continue to work with the OPO Committee to evaluate the use of OPO Metrics to assess performance (Item 9).

4. Program-Related Actions and Personnel Changes: During its December and March meetings, the Committee reviewed and accepted programs changing status by voluntarily inactivating or withdrawing from designated program status. Additionally, during the December meeting, the Committee reviewed 82 and approved 80 Key Personnel Changes. In addition, during the March meeting the Committee reviewed 80 and approved 74 Key Personnel Changes.

5. Due Process Proceedings: During its December meeting, the Committee conducted interviews with five member transplant centers and two OPOs. Summaries of the interviews follow below:

6. Enforcement of Mandatory Donation after Cardiac Death (DCD) protocols: During the December meeting, the Committee received an update on a transplant hospital that has been non-compliant with submitting a certification statement attesting that they have and employ a mandatory DCD organ recovery protocol. The hospital expressed a willingness to give a presentation on their efforts to comply, however, before the next Committee meeting the center subsequently submitted a certification statement attesting that they have and employ a mandatory DCD organ recovery protocol. This hospital adopted the required mandatory DCD policy and sent its certification statement into the MPSC on March 22, 2010.

7. Living Donor Related Bylaws: During the December meeting, the Committee was updated on the review of the bylaws related to living donor transplantation. A joint work group comprised of members from the MPSC, Living Donor Committee, Pediatric Transplantation Committee, Kidney Transplantation (Kidney) Committee, and the Liver and Intestinal Organ Transplantation ("Liver") Committee had been formed to discuss this issue. Draft proposals were circulated to the Kidney and Liver Committees with a request for feedback to the work group so that it could finalize its proposal. The Liver Committee reviewed the proposal and did not recommend any changes. As of the December meeting the Kidney Committee had not responded.

   The Committee discussed the proposal to modify the bylaws pertaining to living donor liver donation. The Committee agreed, by a vote of 25 For, 0 Against, 1 Abstention, to submit the proposal for public comment during the next available cycle. This amendment will delineate requirements for adult-to-adult and adult-to-pediatric living donor surgeons. The Committee asked that language be added to the proposal to clarify which surgeon receives credit as the primary surgeon splitting the liver.

   The Committee also agreed (by a vote of 26 For, 0 Against, 0 Abstentions), to move the proposed amendments to the living donor kidney bylaws forward to public comment in March with the caveat that if the Kidney Transplantation Committee has significant concerns the work group would be convened to revisit the proposal and revise the proposal if needed. The MPSC would need to review the final proposal but they agreed that it could be done electronically.

   When the Committee met in January, they were informed that this proposal needed to be held until the next public comment cycle in order for more analysis to be performed on the resources required for implementation as substantive database changes may need to be made. Feedback had not yet been received from the Kidney Transplantation Committee.

8. Update on Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data): As required in Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data), transplant programs must report all instances of live donor deaths and failure of the live donor's native organ function within 72 hours after the program becomes aware of the live donor death or failure of the live donors' native organ function.

   During its December, January, and March meetings the Committee reviewed eleven reported living donor kidney and liver adverse events and made the recommendation of no further action. In one case, the Committee did recommend that the hospital appear before the Committee and answer why this case was not reported as required in Policy 12.8.4. This center voluntarily ceased live donor liver transplantation and then attended the requested interview at the March meeting.

9. OPO Performance Metrics Work Group: The OPO Performance Metrics Work Group, comprises members of the OPO Committee and the MPSC and is tasked with developing performance metrics to maximize the utilization of organs. The group has been meeting since April 2008. An ordinal logistic regression model was based on OPTN/UNOS data from June 1, 2000 to May 30, 2007, and included data on donors from whom at least one organ was transplanted. Factors in the model were derived from the deceased donor registration form. Factors that were considered to reflect OPO practices were deliberately excluded from the model. The model concordance was 0.8. From the model, 15 of 58 DSAs were identified as having an actual number of organs transplanted per donor that was significantly below expected ($p < 0.05$). Enhanced analyses have been provided to include more recent data as well as donors from whom no organs were transplanted.

   To facilitate this project, the Work Group distributed DSA specific data to each OPO Executive Director in December. During the January 2010 AOPO Executive Directors meeting, the SRTR presented analyses. Additionally, an Educational Forum is scheduled for May 27, 2010, to facilitate broader sharing of the data and discussions. It is expected after these meetings, the metrics will be in final form, and public comment can begin.

   During the March 2010 meeting, the MPSC was apprised of the ongoing work for this project. The Joint OPO/MPSC Work Group is currently working to identify flagging thresholds for OPOs based on these new data and will continue to update the MPSC as the project continues.

10. Modified Flagging Methodology: Continuing the Performance Analysis and Improvement Subcommittee's goal to review existing performance metrics and the ongoing work with the SRTR staff in modifying post-transplant outcome flagging methods, UNOS staff has conducted several retrospective analyses of the modified flagging criteria proposed by the SRTR. In summary, the analysis showed that using the proposed method, the Committee would flag fewer programs overall, while flagging more medium and high volume programs. The analysis also showed that the proposed method would flag >80% of the programs considered "true positives" using the current flagging method and would flag fewer of the current false positives.

    During the December meeting, the MPSC reviewed the recent retrospective analysis and recommended before adoption that the SRTR conduct a simulation analysis. The modified flagging method, while capturing some of the small volume programs, will not capture all small volume programs. Five programs that would not have been reviewed if the modified flagging were in use were considered"true positives." As such, the MPSC wishes to identify a hybrid flagging model that would utilize the modified flagging methodology with some sort of small volume flag. The SRTR reported the simulation may take up to six months.

    During the March MPSC meeting, no further discussion of this topic occurred; the Committee is waiting for the SRTR simulation results before further investigating this change.

11. Composite Pre-Transplant Metric (CPM): A report from the CPM work group was provided to the MPSC during the December meeting. The work group has requested that staff conduct a retrospective analysis of approximately 60 programs (30 liver and 30 kidney), both those flagged by any of the six different proposals and those not flagged. The work group expects to meet three times before the March meeting to review the data for these programs.

A brief overview of the project and potential thresholds for flagging was provided to the MPSC during its March 2010 meeting. The work group will be meeting in person on April 28 to further analyze flagging methods.

12. Intestinal Transplant Program Requirements: During its October 2008, meeting the MPSC agreed to ask the Liver and Intestinal Organ Transplantation Committee (Liver Committee) for input regarding activity levels for intestinal transplant programs as discussed by the Performance Metrics and Certification Work Group and for an update regarding their efforts to develop membership criteria for intestinal transplant programs. At present, intestinal transplant programs are not evaluated on an ongoing basis for activity, performance, or staffing.

    The Liver Committee developed draft proposal of qualifications for an intestinal transplant program and sought the MPSC's input. The proposed requirements were circulated to the MPSC members by email on November 9, 2009, with a request for input. The Committee reviewed a first draft of the proposed language and provided comments back to the Liver Committee. During the December meeting, Dr. Pomfret summarized the ongoing efforts of the Liver Committee, and that the Committee had been working with the ASTS and other experts to develop the proposed requirements.

    The MPSC encourages the Liver Committee to keep working on the proposal. They agreed that the intestinal rehab program is important to the success of the program and that it must be addressed in the requirements. It also asked that the impact of the proposed new requirements on the existing programs be evaluated.

13. Qualifications for Directors, Liver Transplant Program Anesthesiology: During the December meeting, the Committee discussed a memorandum from the American Society of Anesthesiology (ASA), which has suggested qualifications for the directors of liver transplant anesthesia. This recommendation is based on peer review papers that show that liver transplant programs have better outcomes when they utilize an anesthesiologist experienced in liver transplantation. The Committee asked staff to mock up the qualifications into bylaw format and to analyze the resources needed. A draft proposal was shared with the Committee during its March meeting. The Committee reviewed a draft proposal during its March meeting. It appreciates the work done by the ASA and agreed that it should seek input from the Thoracic Organ Transplantation Committee to see if there is a need to develop similar recommendations for heart and lung transplantation. The referral will be made once the work group has finalized the language.

14. Data Coordination Responsibilities and Guidelines: The Committee previously sent a memo to the OPO, Histocompatibility, Transplant Administrators, and Transplant Coordinators Committees requesting feedback on codifying the responsibilities and expectations for primary data coordinators in the bylaws. Responses from each of the Committee's were reviewed with the MPSC. Further, an internal working group of UNOS Staff is evaluating improving data reporting through standard definitions and user guidance within UNet^{sm} and DonorNet®. This UNOS Staff working group will be disseminating additional information regarding their efforts in the coming months and the MPSC recommended incorporating the constituency Committee feedback when this information is available. The Committee will consider this project as the information becomes available, recognizing that bylaw language will be drafted to codify data coordination responsibilities in the coming year. No additional MPSC discussions occurred since the December 2009 meeting, pending the status of the other work groups addressing this project.

15. Separate Transplant Hospitals Seeking Single Program Approval Together: Staff reported to the Committee that requests are being received to consider approving a single, system wide organ transplant program in situations where there are either two established and separately approved transplant programs or application is being made for a new program application as an extension at another transplant hospital within the health system. Simply put, one OPTN/UNOS approved transplant program operated between two member hospitals. The Committee suggested the need to consider updating the MPSC's June 1999 guidelines entitled "Issues in Defining a UNOS Member Transplant Hospital," but felt that additional data was needed to make any practical decisions. The case that the presence of a single CMS provider number for multiple transplant programs within a "transplant hospital" organizational structure should be considered a strong argument that multiple transplant programs should be approved as a single program was noted. A HRSA representative indicated that this could not be used as a sole consideration when seeking single transplant program approval. This view is supported by CMS in their Federal Register comments rejecting consortium approval as single transplant programs. HRSA is currently preparing a formal response regarding this issue and the Committee agreed to readdress the issue once this guidance is received.

16. Transplant Physician Bylaws with Sunset Clause: Staff pointed out to the Committee that several sections bylaws pertaining to training of the primary physician would sunset as of January 1, 2010. These pathways include the ones for nephrology, endocrinology, diabetology, or gastroenterology fellowship training program as the sole training period. With this change, all individuals qualifying by fellowship must have completed an additional 12-month transplant medicine fellowship.

17. Proposal to Add Valuable Consideration Disclosure to Bylaws: Under this proposal, transplant centers would be required to document that potential living organ donors have been informed that the sale or purchase of human organs (kidney, liver, heart, lung, pancreas, and any other human organ) is a federal crime. The MPSC discussed the pros and cons of this proposal, including the burden to transplant centers and the potential need for site auditors to verify the documentation in the centers records. Committee members expressed concern about the practice of developing bylaws in response to a particular incident but ultimately, the Committee agreed to support the proposal by a vote of 19 For, 5 Against, and 2 Abstentions.

    The Committee did recommend that items #7 and #8 under both living donor kidney and living donor liver be re-worded and combined into one item under each organ.

18. Referral from AST/ASN Fellowship Requirements: During its January 25 meeting, the Committee discussed a letter from the AST/ASN requesting the inclusion of a new alternate pathway for primary kidney transplant physician qualifications be added to the bylaws. The Committee agree to further study this proposal and a work group was formed. This proposal is also under review by the Kidney Transplantation Committee.

19. Primary Laboratory Directors Serving in Multiple Labs: The MPSC asked the Histocompatibility Committee to review those situations where a single individual is designated as the primary laboratory director for more than one laboratory and clarify how the time commitment to each laboratory is evaluated when a proposal to add a part-time directorship is made to UNOS and supported by either of the accrediting agencies (ASHI or CAP). The Histocompatibility Committee responded that if the accrediting agency had approved an interim plan for a laboratory while it was going through the approval process that it could recommend to the MPSC that the laboratory be approved for membership. The Histocompatibility Committee also said that if a laboratory received approval under an interim plan, the Committee should be updated every three

months on the laboratory's status until the laboratory reaches final approval. The MPSC reviewed this response during its January call and the considered the issue closed for now.

20. Notification of Changes in Key Personnel: During the March meeting, the Committee discussed the timeliness of notifications and submission of applications for changes in key personnel in transplant programs as it pertains to the bylaw changes that were made last year. Discussion centered on the process that should be followed when members fail to comply and if the circumstances could be quantified so that decisions would be both consistent and fair. The Committee asked that staff provide details about each situation, including a time line. There was a concern that members may not be providing timely notice because of a perception that proprietary information provided to UNOS is not protected. The Committee agreed that a small group should work on the details and bring suggested guidelines back to the MPSC for further discussion.

21. Pediatric Program Requirements: During its discussion of a particular key personnel change application during the December meeting, the Committee expressed its concern that the requirements are not specific for pediatric transplantation.

    The Committee felt that it is time to re-evaluate the bylaws for pediatric programs to delineate that the named primary transplant surgeon must have either training and/or experience in pediatric transplantation. The Committee was concerned that surgeons who perform adult transplants, and who have who have little to no experience in pediatric transplantation, are sometimes being named as the primary surgeon for a pediatric program in order to satisfy the minimum requirements. This practice is not prohibited in the bylaws, but leads to concerns of patient safety and speculation about whether or not the named person is going to be functioning as the primary surgeon or if they were submitted just to satisfy the requirements. The Committee does not feel that such an individual meets the spirit of the requirements and was especially concerned about the differences between adult and pediatric heart transplantation. While it did not have data to review at the time of the discussion, the Committee suggested that the majority of primary transplant surgeons named for pediatric programs are adult surgeons who also perform pediatric transplants.

    The Committee agreed to ask the Pediatric and Thoracic Organ Transplantation Committees to revisit the requirements and to make specific recommendations for amending the bylaws as appropriate to address pediatric transplant expertise in the surgeon requirements. The current "pediatric pathway" was implemented in 2002 as an interim step while the Pediatrics Committee was developing a proposal for pediatric program requirements. The Committee would also consider any other recommended changes to the bylaws that pertain to pediatric program requirements.

22. Pediatric Committee Response Concerning Liver Status 1A/1B requirements: The Committee requested that the Pediatric Committee reevaluate the current listing criteria that require candidates to be admitted to the ICU to achieve status 1A/1B and determine whether the use of candidate location (ICU) as a surrogate for severity of illness remains appropriate and advisable. The MPSC reviewed the OPO Committee's response at its December 2009 meeting.

    The Pediatric Transplantation Committee reported to the MPSC that its discussion centered on potential differing interpretations of what is considered an ICU, the varying approaches programs take to list a candidate and abide by all the policy requirements, as well as the various challenges posed by the policy requirement that a pediatric candidate must be located in an ICU to be listed as Status 1A or 1B. The Committee agreed that submitting an exception to the respective Liver

Review Board is an effective workaround; however, if a pediatric candidate's location in the ICU is not viewed as critical in determining their severity of illness/allocation status, then the requirement that a pediatric patient must be in the ICU to be listed as a Status 1A or 1B should be removed.

The Pediatric Transplantation Committee unanimously supported removing the requirement that a pediatric Status 1A or 1B candidate be admitted to an ICU. Depending on the data gathered and whether more evidence is needed, the Committee will work with the Liver and Intestinal Transplantation Committee to address ICU admittance as a requirement for pediatric liver candidates to be listed Status 1A/B.

23. Patterns and Trends of Member Compliance and MPSC Actions: During the Committee's December and March meetings, staff presented summaries of trends of policy violations on OPO and transplant center site surveys, as well as a summary of issues reviewed by allocation analysts. Site survey information included top policy violations found during site surveys broken down by program, and whether the violations remained during the follow up site survey. The allocation information included types of issues the allocation analysts review, the trends in numbers of issues identified, and the methods in which these issues come to the attention of the allocation analysts. In addition, staff presented types of allocation deviations found during allocation analysis and other reports to UNOS, as well as Committee actions on past potential policy violations. Staff analyzed data by region and method of reporting. Staff presented a possible path for future trend analysis to the Committee. The Committee agreed with the proposed path for continuing analysis.

24. Establishment of Processes to Enforce Standards for Individuals Procuring Deceased Donor Organs for Transplantation: During the March meeting the Committee reconsidered the proposal from the ASTS entitled "Recommendations for Standards for Individuals Procuring Deceased Donor Organs for Transplantation." The ASTS is asking the OPTN to consider incorporating the proposed requirements into policy or bylaws to oversee procuring surgeon qualifications and behavior during solid organ procurement. One of the motivations for the is proposal is that the 2006 CMS "Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations" (Title 42, Subpart G, Section §482.326 Condition: Human Resources) specifies that the OPO must ensure that all the individuals who provide or supervise services and qualified to do so; and that *the OPO must have credentialing records for physicians and other practitioners who routinely recover organs in hospitals under contract or arrangement with the OPO and ensure that all physicians and other practitioners who recover organs in hospitals with which the OPO has agreements are qualified and trained*.

    The AOPO has initiated an on-line repository for the credentials of the authorized procurement surgeons, but they do not have universal records, or standardized minimum requirements for granting this authorization, which results in variability between OPOs and DSAs.

    Background:

    In February 2008, the ASTS Council solicited and received feedback on the recommendations from the OPTN Operations and OPO Committees and then forwarded the revised document to the MPSC for consideration. The MPSC considered the revised proposal during its March 2009 meeting, and while the Committee appreciated having the opportunity to comment on the recommendations, it felt the responsibility remained with the ASTS and was not inclined to pursue the development of parallel policies at that time.

The MPSC was asked to reconsider the proposal during its March 2010 meeting. The Committee was reminded that the purpose of the requirements would be to optimize performance of organ recovery for the recipient's, and to improve the functionality of the OPOs and the host hospitals. In addition, recent program and OPO complaints regarding organ recovery behavioral issues made it necessary to look at this request again. The Committee reviewed the minimum organ specific requirements as well as the suggested requirements for DCD. The ASTS' intent is that a licensed MD or DO, trained in surgery and pathology, must be present to provide oversight to the case in the best interest of safety of patients. The Committee was concerned that the recommended requirements would prevent the physician assistants (PAs) that presently perform organ procurements independently from continuing to do so. The Committee suggested that an alternate pathway be developed to accommodate the non-physicians who are currently actively surgically removing solid organs.

The ASTS proposal further suggests that

- OPO's will track quality assessments and enforce any necessary corrective actions through transplant centers;
- Corrective actions may include requirement for further experienced proctoring/training to disallowing a surgeon to recover organs at a DSA; and
- The requirements would be enforced by OPTN/UNOS through MPSC if transplant center not responding adequately. At present, there is not any other venue for discussing the loss of transplantable organs due to surgical complications.

The MPSC agreed that the credentialing requirements are the responsibility of the transplant centers not the OPO [or the OPTN] and that the OPO needs to communicate its concerns about the procurement team (members) back to the hospitals.

The Committee agreed that the focus should be on assessment and risk. They asked about the data used in forming these recommendations, especially those pertaining to the non-physician who procures organs, and raised the following concerns:

- Has an analysis been performed that shows that the occurrence of disease transmission and malignancies is different when the physician versus the non-physician does the procurement?
- Has there been analysis of the point in the process where the omission occurs when there is a case of disease transmission? Is there data that can relate it to the level of experience of the procuring surgeon/non-physician?

The Committee noted that name of the procuring surgeon is not recorded in the database so that information is not available through the OPTN for analysis.

With regard to the proposed requirements, the MPSC made the following observations:

- A procuring surgeon might be expected to provide oversight to a non-physician from the OPO who is there to procure other organs.
- If the fundamental goal is to provide patient safety from infectious disease and cancer, the qualifications inadequately address marginal and older donors.
- The surgeon who meets the minimal numbers to qualify might not have enough experience to make the assessment.
- Many donor operations are performed by transplant fellows, who may have less experience than the non-physicians.
- A technician/PA would not be able to recover organs as independent surgeons.

- An alternative pathway is needed for the physician assistants (PA) who perform organ procurements. The Committee acknowledged that the number of PA's is limited and that it was unlikely that new PA's would become involved. Could PA's be evaluated on a case-by-case basis to see if their competency level is equivalent to that of the physicians?
- Liver – in situ splits – procuring surgeon may need special experience for these.
- The issues of maintaining currency needs further discussion.
- The qualifications for DCD need further discussion.

Suggestions:

- Add requirement that procuring surgeons must participate in an orientation with the OPO.
- Dr. Mulligan reported that he would need to take the MPSC recommendations to add a pathway for PA's back to the ASTS Council.
- The Committee agreed that the proposal needs more work and did not vote on a specific recommendation. The Chair will work with the staff to develop a path forward. If the proposal were pursued then an analysis of resources would need to be performed. Additionally, the proposal would need further review by the various OPTN Committees to ensure that they have reached a consensus on the proposed language. Input is especially needed from the thoracic community, at least the Thoracic Organ Transplantation Committee, before the MPSC could consider sponsoring or co-sponsoring a proposal.

25. Impact of OMB Forms Changes on Performance Reviews: Staff presented an overview and the timeline for the process of adopting modifications to the OPTN data collection forms to the Committee for their input. During the presentation, some of the proposed changes were highlighted. The Committee was advised that most of the added data elements in the proposal are intended to enhance risk-adjustment for the program-specific reports.

26. Living Donor Pilot Program: The Committee was briefed on the DEQ pilot survey of five living kidney donor programs conducted in February and March 2010. DEQ staff used a newly developed survey plan including review of the programs' living donor protocols and compliance with the same, review of data, staff interviews, and tracer methodology to verify awareness of program protocols. Observations and findings from the first five pilot surveys will be reported to the MPSC in July 2010. Site surveyors are conducting an additional five pilot surveys in May, June, and July 2010, which will be reported to the MPSC in December 2010.

27. Voting Status of Hospital Based OPOs and Laboratories: The Committee reviewed a June 26, 2009, letter that was co-signed by the executive directors of the eight hospital based organ procurement organizations (OPOs). In the letter, they asked the MPSC to consider modifying the voting structure of the OPTN/UNOS to allow for hospital-based OPO's to have a vote on regional and national matters. Historically, these OPOs have been considered a part of the parent member (the transplant hospital) under which they applied, and they have shared a single institutional vote.

    The Committee agreed that this request should be further reviewed and that at the same time the voting status of hospital-based laboratories should be examined. A work group was established to review this issue and report to the full Committee.

    During the December meeting, the Work Group informed the Committee of its discussion pertaining to ways to amend the voting process. The Work Group considered the options of "no change," voting only at the regional level, and voting at the national level. Other than not making

a change the easiest approach would be to allow voting only at the regional level because it would have less impact on the current member structure as defined in the bylaws; but even this change would require amending the bylaws.

Staff presented an analysis to the Committee that showed the impact of changing the voting allowances at the national level. In five regions, the balance of votes would change such that the non-transplant hospital members would form the majority. In two additional regions, the transplant hospitals and non-transplant hospitals would be equal. Based on the potential impact of this change and the anticipated resources that are needed for implementation, the Committee agreed that this might not be the best time to pursue these changes. Staff will continue to work with the chair on this matter.

Figure 1: Analysis of voting members and potential impact if HLAB and HOPO given a separate vote

Region	TXC	HOPO	IOPO	HLab	ILab	*Other members	Total potential votes non TXC
1	**14**	0	2	7	3	4	**16**
2	**34**	0	5	14	5	8	**32**
3	**27**	2	8	11	6	3	**30**
4	**33**	0	4	7	9	1	**21**
5	**33**	1	7	10	10	0	**28**
6	**9**	1	2	1	3	2	**9**
7	**22**	2	2	11	4	0	**19**
8	**18**	0	5	6	5	2	**18**
9	**16**	1	3	7	4	3	**18**
10	**20**	0	6	10	4	4	**24**
11	**24**	1	6	12	5	5	**29**
	250	8	50	96	58	32	**244**

Based on data as of November 2009

*= Individual, Public org, Med/Scientific Professional Organization

28. UNOS Actions: During the December meeting, the Committee members unanimously agreed that actions regarding Bylaws, Policy, and program-specific decisions made during the OPTN session would be accepted as UNOS actions.

    ** RESOLVED, that the Committee accepts those program specific determinations made during the meeting as UNOS recommendations. FURTHER RESOLVED, that the Committee also accepts the recommendations made relative to Bylaw and Policy changes.

During the March 24-25, meeting the Committee unanimously approved the same resolution relative to actions taken during that meeting.

Participation at the Membership and Professional Standards Committee Meetings
December 9-10, 2009, January 25, 2010, and April 28, 2010

NAME	Committee Position	July 22-23, 2009	Sept 25, 2009 Conf Call	Dec 9-10, 2009	Jan. 25, 2010 conf call	March 24-25,2010	Apr 28, 2010
Charles Alexander RN, MSN, MBA, CPTC	Chair	X	X	X	X	X	X
David Mulligan, MD	Vice Chair	X	X	X	X	X	X
Elizabeth Pomfret, MD, PhD	Regional Rep.	X	X	X	X		X
David Klassen, MD	Regional Rep.	X			X	X	X
Christopher Hughes, MD	Regional Rep.	X	X	X		X	
David Nelson MD	Regional Rep.	X	X	X		X	
Christopher Marsh MD	Regional Rep.	X	X	X		X	X
Karen Nelson Ph.D., D(ABHI)	Regional Rep.	X	X	X	X	X	X
Yolanda Becker MD, FACS	Regional Rep.	X *	X	X			X
Susan Dunn, MBA, RN, BSN	Regional Rep.	X	X	X	X	X	X
David Conti MD	Regional Rep.		X	X	X		
Steven Rudich, MD, PhD	Regional Rep.	X*	X	X	X	X	X
Prabhakar Baliga, MD	Regional Rep.	X	X	X		X	X
Abbas Ardehali, MD	At Large	X		X		X	X
Sharon Bartosh MD	At Large	X	X	X	X		X
Elaine Berg, MPA, FACHE	At Large	X	X	X	X	X	
Jonathan Chen MD	At Large	X	X	X		X*	X
Todd Dewey MD	At Large	X					
Udeme Ekong, MBBS, MRCP	At Large	X		X		X	X
Barry Friedman RN, BSN, MBA, CPTC	At Large	X	X	X	X	X	X
Benjamin Hippen M.D.	At Large	X	X	X	X	X	
Marjorie Hunter, ESQ	At Large	X	X	X		X	X
Ian Jamieson MBA, MHA	At Large	X	X		X	X	X
David Marshman, CPTC, BS	At Large	X	X	X	X	X	X
Jerry McCauley MD, MPH	At Large	X	X	X	X	X	X
Michael Mulligan MD	At Large	X					
Claus Niemann M.D.	At Large	X		X	X	X	X
Todd Pesavento, MD	At Large	X	X	X	X	X	X
Shirley Schlessinger, MD	At Large	X	X	X	X	X	
Roshan Shrestha, MD	At Large	X		X		X	
Betsy Walsh, JD, MPH	At Large	X	X	X	X	X	
Mark Zucker, MD, JD	At Large	X	X	X		X	X
Christopher McLaughlin	HRSA	X		X	X	X	X
Robert Walsh	HRSA	X	X	X	X	X	X
Charlotte Arrington MPH	SRTR Liaison	X	X	X		X	X
Jack Kalbfleisch	SRTR Liaison	X					

NAME	Committee Position	July 22-23, 2009	Sept 25, 2009 Conf Call	Dec 9-10, 2009	Jan. 25, 2010 conf call	March 24-25,2010	Apr 28, 2010
Robert Wolfe, Ph.D.	SRTR Liaison	X		X			
Emily Messersmith	SRTR representative				X		
Sally Harris Aungier	Committee Liaison	X	X	X	X	X	X
David Kappus MAS	Committee Liaison	X	X	X	X	X	X
Manny Carwile	Support Staff			X		X	X
Elizabeth Coleburn	Support Staff	X	X	X	X	X	
Susan Duerkson	Support Staff			X		X	
Rosey Edmunds	Support Staff	X	X		X		
Erick Edwards Ph.D.	Support Staff	X	X	X	X	X	X
Mary D Ellison, Ph.D.	Support Staff	X		X	X	X	X
Suzanne Gellner JD, CHC	Support Staff	X	X	X	X	X	X
Linda Gobis, BS, MN, JD	Support Staff	X		X	X	X	X
Diana Marsh	Support Staff	X					
Karl McCleary Ph.D., M.P.H.	Support Staff	X	X	X	X	X	X
Kevin Myer	Support Staff	X	X	X	X	X	X
Heather Neil	Support Staff	X			X		X
Joel Newman	Support Staff			X		X	
Jacqueline O'Keefe MBA	Support Staff	X	X	X	X	X	X
Ann E Paschke	Support Staff	X					
John Persons	Support Staff						X
Amy Putnam	Support Staff	X		X		X	X
Sharon Shepherd	Support Staff			X	X	X	X
Mariam Siddiqui	Support Staff			X			
Leah Slife	Support Staff		X		X	X	
Darren Stewart	Support Staff	X					X
Robyn Zernhelt	Support Staff		X	X	X		X
Thomas Hamilton, CMS	Guest	X					

* Participated by conference call

Exhibit A

Mini-Brief **OPTN/UNOS**

Proposal to revise the OPTN and UNOS bylaws to allow more flexibility in delivery options for correspondence between OPTN and Members, and Members and Patients

Affected/Proposed Policy: OPTN Bylaws Article I, 1.11 (Removal of Non-Qualifying Members) and 1.12 (Meetings); Article II, 2.6 (Meetings); Article X, 10.2 (Notice); Appendix A, 2.04A (Requests), 2.11 (Procedural Rights), 3.01A (Definition of "Adverse"), 3.02A (Hearings), 3.03A (Appellate Review), 4.01A (Board of Directors Action), 6.03A (Default in Payment of Reimbursable Cost and Expenses); and Appendix B, II. C. (Functional Inactivity, Inactive Transplant Program Status, Relinquishment of Designated Transplant Program Status and Termination of Designated Transplant Program Status)

UNOS Bylaws Article I, 1.11 (Removal of Non-Qualifying Members) and 1.12 (Meetings); Article II, 2.6 (Meetings); Article X, 10.2 (Notice); Appendix A, 2.04A (Requests), 2.11 (Procedural Rights), 3.01A (Definition of "Adverse"), 3.02A (Hearings), 3.03A (Appellate Review), 4.01A (Board of Directors Action), 6.03A (Default in Payment of Reimbursable Cost and Expenses), and Bylaws, Appendix B, II, C (Transplant Hospitals, Functional Inactivity, Inactive Transplant Program Status, Relinquishment of Designated Transplant Program Status and Termination of Designated Transplant Program Status).

Sponsoring Committee: Membership and Professional Standards Committee (MPSC)

Summary and Goals of the Proposal:

The proposed modifications to the OPTN and UNOS bylaws would broaden the language that describes how correspondence required by the bylaws should be delivered between the OPTN and members, and members and patients. Currently, the bylaws limit delivery of many communications to specific services that are provided by the United States Postal Service (USPS). The proposed language would accommodate modern delivery methods that meet the needs for security and tracking, and provide faster and, often, less costly service than the currently required USPS services. In addition, the more general proposed language allows for use of future innovations in delivery methods without an additional revision to the bylaws.

Background and Significance of the Proposal:

When the current provisions were drafted, the accepted method to send correspondence was through the USPS. Certainly, if tracking, security and the ability to prove date of receipt were important, certified or registered mail with return receipt was the safest way to ensure that communications were delivered appropriately at that time. Today, there are multiple options for delivery of correspondence that are safe, secure, and less costly. Therefore, the language of the bylaws is too limiting. The USPS often takes days to deliver mail, particularly mail requiring special handling. In addition, it can be very costly to send communications through the USPS, especially when certified, registered or return receipt requested services are used. Recently, a letter from the Membership and Professional Standards Committee (MPSC) notifying a member of a resolution of the committee took ten days from the date it was sent to be delivered certified mail, return receipt requested. The bylaws give members who are entitled to an interview or hearing 14 days from date of receipt of the MPSC letter to request the

interview or hearing. The time between meetings is limited to prepare for interviews or hearings. Therefore, it is important that members receive their letters in a timely manner, so that the member, as well as the UNOS staff, can have the optimal amount of time to prepare for an upcoming interview or hearing. There are a number of options for delivery of communications that can meet the needs of the OPTN including the ability to track the correspondence, the ability to determine the date of receipt and assurance that the correspondence is being sent securely. All of the options included in the proposed language are secure, can provide the required information, and can provide fast delivery to the member. Specifically, the secure electronic communication methods also are cost effective because there is no transaction cost.
The Committee reviewed and endorsed the proposal as written by a vote of 23 For, 0 Against, 0 Abstentions when it met on March 24-25, 2010.

**** RESOLVED, that Article I, Article II, Article X, Appendix A and Appendix B of the OPTN Bylaws and Article I, Article II, Article X, Appendix A and Appendix B, II, C of the UNOS Bylaws shall be amended as set forth in below, effective pending notice to the membership.**

The proposed revisions were not distributed for public comment because the proposed revisions would not affect allocation of organs or have membership services implications. The following proposed language would replace references to USPS services wherever it appears in the bylaws.

- **Collaboration:** The proposal was developed in conjunction with the department of evaluation and quality and the legal department of UNOS.

- **Alternatives considered:** Different delivery methods were considered to determine if there was appropriate security, ability to be tracked and the ability to prove date of receipt with consideration of the cost involved. Any method that could not meet all of the above criteria, such as email, was not included in the proposed language.

- **Strengths and weaknesses:** The proposed bylaw revision will benefit the transplant community by providing more options for delivery of correspondence. Many of the options that will be available under this revision are faster and less costly than the current required delivery method. However, if preferred, the current method of delivery is still available since the broad language utilized in the proposed revision allows the use of the current United States Postal Service options. The broader language also provides the ability to accommodate future delivery innovations without requiring another bylaws revision. The use of broader language in the proposal could lead to some confusion about what delivery services would be appropriate. To minimize the confusion, examples of delivery options that would be appropriate have been provided parenthetically following the new language.

- **Description of intended and unintended consequences**: The proposed bylaw revision will result in more timely and less costly communication between UNOS and members, and members and their patients for the required notifications under the bylaws.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

The proposed bylaw revision will provide options for delivery of correspondence that are more cost effective and timely than those currently contained in the bylaws. These benefits will improve efficiency in communications between UNOS and members, which promotes the program goal of operational effectiveness.

HHS Program Goals	*Strategic Plan Goals*
Operational Effectiveness	The OPTN will identify process and system improvements that best support critical network functions, and work to disseminate them to all members who could benefit

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

Implementation of the proposed bylaw revision does not require significant actions by members or UNOS to comply. The revision merely broadens the delivery options that are currently available for correspondence between UNOS and members and from members to patients. The current delivery requirements have not been deleted so UNOS and members can continue to use the United States Postal Service delivery services. However, in addition to those services, UNOS and members will have the option of utilizing commercial overnight services, secure electronic communications such as secure email, or any other delivery method that is appropriate for that category of correspondence as determined by the bylaws. No programming in UNet℠ will be required. One of the new options that will be available under this proposal, secure email, is being implemented for use with correspondence not covered by the bylaw provisions. Therefore, members will have some experience with this new delivery tool prior to implementation of its use for correspondence covered by this proposed bylaws revision. During the transition to the new delivery methods, multiple methods of delivery will be used to ensure receipt and to give members the opportunity to become acclimated to the new delivery methods.

Communication and Education Plan:

UNOS has begun to publicize the use of secure email for communications that are not currently required to be delivered by a specific method in the bylaws. These communications have included notice that it is anticipated that in the near future, all communications will be eligible to be sent by secure email, as well as other delivery methods.

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
UNOS Communications e-newsletter	Transplant professionals	email	

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Update news magazine	Transplant professionals	mail	March-April 2010
Routine department of evaluation and quality correspondence	Transplant professionals	Mail, email, fax	Ongoing
Policy Notice	Transplant professionals	email	One month post board approval

Monitoring and Evaluation:

The proposed bylaws revision does affect monitoring and evaluation of members.

Policy or Bylaw Proposal:

OPTN BYLAWS, ARTICLE I, MEMBERS

1.11 Removal of Non-Qualifying Members.

a. Transplant center Institutional Members that fail to qualify as an OPTN Member under Article 1.2(b) shall be treated in accordance with Article II of Appendix B to these Bylaws.

b. All other OPTN Members who cease to qualify for OPTN membership under Article I of these Bylaws may be removed as OPTN Members in accordance with the following procedures:

1. The Member may request removal from OPTN membership by forwarding a written request therefor to the OPTN, or

2. Even if the Member does not request removal, the OPTN may notify the Member in writing that, unless the Member demonstrates that it continues to meet applicable membership criteria within sixty (60) days of notification, the Member's OPTN membership will be terminated.

i. If, within sixty (60) days of such notification, the Member demonstrates, to the satisfaction of the OPTN, that the Member continues to meet OPTN membership requirements, the OPTN shall withdraw its notice of termination.

ii. If the Member fails to demonstrate that it continues to meet applicable OPTN membership requirements, its membership in the OPTN will terminate on the sixtieth (60th) day after notification of termination by the OPTN. The Member can appeal this decision to the Secretary of HHS. In the event a Member exercises this right of appeal, the Member shall notify the OPTN Contractor of this exercise by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested) ~~registered or certified mail, return receipt requested~~. Pending a decision on the appeal, the process defined by these procedures shall continue unless the Secretary directs otherwise. In the event the appeal is denied, the process shall be further continued or reinitiated, as applicable. Any other decision on the

appeal by the Secretary shall be submitted to the Membership and Professional Standards Committee or Board of Directors as appropriate for action consistent with the Secretary's decision.

c. Any Member that requests removal from OPTN membership or is otherwise removed from OPTN membership under this Article 1.11 may later re-apply for membership in accordance with Article 1.7 of these Bylaws.

1.12 **Meetings**. The annual meeting of the Members to elect a Board of Directors pursuant to Article 2.1 of these Bylaws, to elect Principal Officers pursuant to Section 6.1 of these Bylaws and to address such other matters as may be appropriate shall be held in February or March of each calendar year and may be held in conjunction with the annual meeting of the Board of Directors. Special meetings of the Members may be called at any time by the President, Executive Director, or a majority of the Board of Directors, or by written application of a majority of the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Member Electors, Public Organization Member Electors, Medical/Scientific Member Electors, and Individual Member Electors stating the time, place, and purpose of the meeting. Members attending meetings shall do so at no cost to the OPTN. Meetings of the OPTN membership typically shall be open to the public; however, discussions involving confidential matters including, OPTN member admission, credentialing, monitoring, or disciplinary matters and matters involving individuals' privacy where disclosure would constitute a clearly unwarranted invasion of personal privacy, shall be reserved for closed sessions as appropriate and consistent with the OPTN Contract. Representatives from the Federal government serving on the Board of Directors, or their designees, shall not be precluded from attending such closed sessions of OPTN meetings.

Written notice of any regular or special meeting of the Members shall state the date, time, and place of the meeting and the purpose for which the meeting is called, and shall be ~~mailed~~ provided to each Member not fewer than 25 or more than 60 days before the date of the meeting. Giving notice of a meeting of Members to a Member or Member Elector who is not eligible to vote does not imply that the Member or Member Elector may vote.

A written waiver of notice signed at any time by a Member or Member Elector shall be the equivalent of any notice required herein. A Member or Member Elector who attends a meeting shall be deemed to have had timely and proper notice of the meeting unless the Member or Member Elector attends for the express purpose of objecting that the meeting is not lawfully called or convened.

Article II
Board of Directors

2.6 **Notice of Meetings.** Written notice of any regular or special meeting of the Board of Directors shall state the place, date, and time of the meeting and shall be ~~mailed~~ provided to each Director at the address on file with the Executive Director not fewer than 10 or more than 60 days before the date of the meeting. The Executive Director shall circulate the agenda for each Board of Directors meeting to the Members at least 10 days prior to the meeting in order to promote input from the Members to the Directors. A written waiver of notice signed by a Director, whether before or after the time stated therein, shall be the equivalent of the giving of any notice required herein. A Director who attends a meeting shall be deemed to have had timely and proper notice thereof.

Article X
Amendment of Charter and Bylaws

10.2 **Notice.** Notice of any meeting at which an amendment to the Charter or Bylaws is proposed shall be ~~sent by mail~~ provided to each Director at the address on file with the Executive Director no fewer than 10 or more than 60 days before the date of the meeting, accompanied by a copy of the proposed amendment.

APPENDIX A TO BYLAWS - OPTN
Application and Hearing Procedures for Members and Designated Transplant Programs
Corrective Action and Enforcement of OPTN Requirements
OPO, Transplant Hospital, and Histocompatibility Laboratory Members

2.04A - Requests

All requests for corrective action to enforce OPTN requirements shall be submitted to the MPSC in writing by the Executive Director or his/her designee, and shall be supported by reference to the specific activities or conduct which constitute the grounds for the request. The Executive Director, or his/her designee, shall promptly give notice of such request for corrective action to the Member by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested)~~registered or certified mail, return receipt requested~~.

2.11A - Procedural Rights

Procedural rights, including "interviews and hearings," are further described in Section 3.01A – 3.03A of the Bylaws. If the Member does not deliver a written request for an interview to the chairperson of the MPSC or the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) ~~certified or registered mail~~ within 14 days following his receipt of such notice, the Member waives it rights to an interview and the MPSC may proceed to implement its proposed action.

Interviews and Hearings

3.01A - Definition of "Adverse"

(1) **Recommendations or Actions**: Subject to Section 3.01a (4) below, the following recommendations or actions shall, if deemed adverse pursuant to Section 3.01a (2) below, entitle the applicant or Member affected thereby to a hearing:

(a) Rejection of initial membership or rejection of designation as a transplant program;

(b) Probation;

(c) Initial declaration of Member Not in Good Standing and subsequent determinations not to restore the Member to unrestricted membership status;

(d) Suspension of membership privileges either directly or after a period of probation;

(e) Termination of membership, either directly or after a period of probation or suspension.

(f) Any other action specified in Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c), including, by way of example and not limitation, removal of designation as a transplant program.

(2) **When Deemed Adverse**: A recommendation or action listed in section 3.01a (1) above shall be deemed adverse only when it has been:

(a) Recommended by the MPSC or, in the case of: (i) rejection of initial membership, (ii) rejection of designation as a transplant program, or (iii) findings with respect to Category I potential violations, recommended by a Subcommittee of the MPSC; or

(b) Taken by the Board of Directors or the Executive Committee contrary to a favorable recommendation by the MPSC or subcommittee of the MPSC under circumstances where no right to a hearing existed; or

(c) Taken by the Board of Directors or the Executive Committee on its own initiative without benefit of a prior recommendation by the MPSC.

(3) **Interviews:** Except in the case of Category I potential violations, when the MPSC or MPSCPCSC is considering making an adverse recommendation concerning an applicant or a Member or issuing a letter of reprimand, or when an organ-specific committee refers a matter to the MPSC/MPSC-PCSC with a recommendation that the MPSC consider such an action under Section 2.05A above, the applicant or Member shall be entitled to an interview before the MPSC or the MPSC-PCSC. The interview shall not constitute a hearing, shall be preliminary in nature, and shall not be conducted according to the procedural rules provided with respect to hearings. The applicant or Member shall be informed of the general nature of the circumstances and may present information relevant thereto. A summary record of such interview shall promptly be made by the MPSC and a copy promptly provided to the applicant or Member who was granted the interview. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of OPTN requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the Member has not had the opportunity for an interview and/or other procedural rights described below.

Members shall not be entitled to an interview in the case of Category I potential violations; or if action is being considered pursuant to 5.05A or 5.07A of these Bylaws.

(4) **Right to a Hearing**:

(a) An applicant or Member shall have the right to one hearing proceeding, and subsequent appellate review unless the Board of Directors conducts the hearing, with respect to any application for membership, application for designation as a transplant program, and request for corrective action to enforce membership requirements in which an adverse recommendation or action is taken. The hearing may be requested upon the first to occur of the adverse recommendations or actions listed in section 3.01A(1) above or, if waived at such time by the applicant's or member's failure to request a hearing within the time and in the manner specified in section 3.02A below, upon any subsequent adverse recommendation or action arising out of the same application for membership, application for designation as a transplant program, or request for corrective action to enforce membership requirements.

(b) **Category I Potential Violations**. In the case of a determination of time sensitive threat to patient health or public safety in connection with Category I potential violations, the hearing and any subsequent appellate review will commence together with or follow rather than precede the Executive Committee's or the Board's decision regarding and action upon the MPSC subcommittee's recommendation, as set forth below:

(i) The MPSC subcommittee recommendation will be referred immediately to the Executive Committee. At the same time, notice will be given to the Member by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested)~~registered or certified mail, return receipt requested~~, as well as facsimile transmission. Where the finding continues to be a Category I potential violation with time sensitive threat to patient health or public safety, the MPSC subcommittee action shall include a recommendation for designation of the Member to be Member Not in Good Standing and that the offending transplant program or institution voluntarily inactivate, and, failing acceptance of this recommendation to voluntarily

inactivate with immediate action to so inactivate (including notice to and assistance for patients pursuant to OPTN requirements), the MPSC subcommittee shall further recommend approval from the Secretary to suspend member privileges, terminate membership or designated transplant program status, and/or take action specified in the OPTN Final Rule.

(ii) Following receipt of the MPSC subcommittee recommendation, the Executive Committee shall determine whether it or the Board of Directors shall consider the matter and the Executive Committee or the Board, as the case may be, shall consider the same and affirm, modify, or reverse the recommendation or action in the matter. A concise statement of the result and the reasons therefore, and all documentation considered, shall be transmitted to the Executive Director.

(iii) The Executive Director, or his/her designee, shall promptly send a copy of the result to the Member by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested) ~~registered or certified mail, return receipt requested~~ (as well as facsimile transmission), and to the Secretary of HHS within three business days or such longer period as may be necessitated for good cause, as determined by the Secretary, if the decision continues to be adverse to the Member. A copy of the result also shall be forwarded to the MPSC or to the Board of Directors, as determined by the Executive Committee, in the event the Member exercises its rights to a hearing under Section 3.02A of the Bylaws. The Member may request that a copy of the supporting documentation be furnished at the Member's expense.

(iv) Notice of a decision by the Executive Committee or Board that the Member has been placed on probation or declared Not in Good Standing shall be circulated to all Members. The membership shall be notified of decisions by the Executive Committee or Board to recommend to the Secretary of HHS suspension of membership privileges or termination of membership only upon approval of such recommendation by the Secretary.

(v) In the event the Member exercises its right to a hearing, the process described in Section 3.02A will be initiated or continued, as applicable, consistent with the timing of delivery and receipt of notices. The hearing will be before the MPSC, the Board or the Executive Committee as determined by the Executive Committee.

Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of OPTN requirements poses a substantial and imminent threat to the quality of patient care, the Board may take other appropriate action using other appropriate process even if the steps noted above for a Category I proceeding have not been completed or the Member otherwise has not had the opportunity for a hearing and/or subsequent appellate review.

Members will not be entitled to a Hearing in the case that action is being considered pursuant to 5.05A or 5.07A of these Bylaws, except as provided in those sections.

(5) **Right of Appeal to the Secretary.** An applicant for membership or designation as a transplant program shall have the right to appeal decisions of the MPSC, MPSC subcommittees, or the Board of Directors regarding these applications to the Secretary of HHS in accordance with the OPTN Final Rule, 42 CFR Part 121. In the event an applicant exercises this right of appeal prior to exhaustion of the applicant's other procedural rights as described in these Bylaws, the applicant shall notify the OPTN Contractor of this exercise by a method that can be tracked and that

provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested)~~registered or certified mail, return receipt requested~~. Upon receiving such notification, the OPTN Contractor shall notify the Secretary of the status of the matter with respect to these procedures within three business days or such longer period as may be necessitated for good cause, as determined by the Secretary. Pending a decision on the appeal, the process defined by these procedures shall continue unless the Secretary directs otherwise. In the event the appeal is denied, the process shall be further continued or reinitiated, as applicable. Any other decision on the appeal by the Secretary shall be submitted to the MPSC or Board of Directors as appropriate for action consistent with the Secretary's decision.

3.02A – Hearings

(1) **Parties**: The parties to a hearing shall be the applicant or Member against whom an adverse recommendation or action has been taken and the MPSC, the Executive Committee, or the Board of Directors, i.e., the body whose adverse recommendation or action is at issue.

(2) **Notice of Adverse Recommendation or Action**: An applicant or Member against whom an adverse recommendation or action has been taken shall promptly be given notice of such action by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested) ~~registered or certified mail, return receipt requested~~. Such notice shall:

(a) Briefly advise the applicant or Member of the nature of the adverse recommendation or action and the grounds therefor; and

(b) Advise the applicant or Member of the right to a hearing pursuant to the provisions of these Bylaws; and

(c) Specify the number of days following the date of receipt of notice within which a request for a hearing must be submitted; and

(d) State that the failure to request a hearing within the specified time period shall constitute a waiver of rights to a hearing and to any appellate review of the matter; and

(e) State that all materials about the applicant or Member that were generated by or submitted to the MPSC, the Executive Committee, or the Board, as the case may be, prior to that body's adverse recommendation or action, shall be made available to the applicant or Member, upon request, for inspection and copying; and

(f) State that upon the OPTN Contractor's receipt of the hearing request, the applicant or Member will be notified of the date, time, and place of the hearing.

(3) **Request for Hearing**:

(a) Except in the case of Category I potential violations, an applicant or Member shall have14 days following his receipt of a notice to file a written request for a hearing. If the applicant or Member wishes to be represented at the hearing by an attorney, the request for hearing shall include a statement to that effect and identify by name and business address the attorney who will represent the applicant or Member. Such requests shall be delivered to the chair of the MPSC or the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) ~~certified or registered mail~~.

(b) Category I Potential Violations. In the case of Category I potential violations, an applicant or Member shall have seven days following his receipt of a notice to file a written request for a hearing. If the applicant or Member wishes to be represented at the hearing by an attorney, the request for hearing shall include a statement to that effect and identify by name and business address the attorney who will represent the applicant or Member. Such requests shall be delivered to the chair of the MPSC or the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) ~~certified or registered mail~~.

(4) **Waiver by Failure to Request a Hearing**: An applicant or Member who fails to request a hearing within the time and in the manner specified waives any right to such a hearing or any appellate review to which he might otherwise have been entitled. Such waiver in connection with:

(a) An adverse action by the Board of Directors or the Executive committee, shall constitute acceptance of that action, which shall thereupon become effective as the final decision by the Board;

(b) An adverse recommendation by the MPSC or the Executive committee shall constitute acceptance of that recommendation, which shall thereupon become and remain effective pending the final decision of the Board of Directors.

(5) **Notice of Hearing**: Upon receipt of a timely request for a hearing, notification of the time, place, and date of the hearing shall be sent to the applicant or Member by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) ~~certified mail~~ at least 7 days prior to the hearing.

(6) **Statement of Issues**: The notice of hearing described in Section 3.02A(5) above shall contain a concise statement of the issues raised by the adverse recommendation or action which is the subject of the hearing.

(7) **Appointment of Hearing Committees**:

(a) **By MPSC**: A hearing occasioned by an adverse MPSC recommendation shall be conducted by a hearing committee appointed by the chair of the MPSC and composed of three (3) members of the MPSC or in the discretion of the chair, shall be composed of those MPSC members who are in attendance at a regular or special MPSC meeting and are not disqualified under section 3.02A(8) below.

(b) **By Board of Directors**: A hearing occasioned by an adverse action of the Board of Directors may be conducted by a hearing committee appointed by the chair of the Board of Directors and composed of three (3) directors. One of the appointees shall be designated as chair. Alternatively, in the discretion of the chair of the Board, the hearing shall be conducted by those Board Members who are in attendance at a regular or special meeting of the Board, provided that such Members are not disqualified under Section 3.02A(8) below and constitute at least a quorum of the full Board.

(c) **By MPSC-PCSC or Ad Hoc MPSC Subcommittee/Executive Committee or Board in the Case of Category I Potential Violations:** A hearing occasioned by an adverse recommendation from a subcommittee of the MPSC or executive Committee or Board in the case of Category I potential violations shall be conducted by a hearing committee appointed by the chair and composed of at least three (3) members of the MPSC or, in the discretion of the chair, shall be composed of those members who are in attendance at a regular or special meeting and are not disqualified under section 3.02A(8) below, provided that such members constitute at least a quorum of the full committee or Board.

(8) **Service on Hearing Committee**: A MPSC or Board of Directors member shall be disqualified from serving on a hearing committee if he/she has been personally and directly involved in compiling evidence for the OPTN Contractor on the matter at issue.

(9) **Appearance and Representation**: Appearance by the applicant or Member who requested the hearing shall be required. An applicant or Member who fails without good cause to appear and proceed at such hearing shall be deemed to have waived his rights to such a hearing or any appellate review to which it might otherwise have been entitled. The applicant or Member may be represented by an attorney at any hearing or at any appellate review proceeding. The MPSC, MPSC subcommittee, Executive committee, or the Board of Directors shall be allowed representation by an attorney.

(10) **Presiding Officer**: The chair of the hearing committee shall be the presiding officer. The presiding officer shall regulate the course of the hearing to assure that all participants in the hearing have a reasonable opportunity to present relevant oral and documentary evidence and to conduct such cross-examination as may be required for a full and true disclosure of the facts. He/she shall determine the order of procedure during the hearing and shall make all rulings on interpretation or construction of the OPTN Charter and Bylaws and other relevant documents and OPTN requirements on procedure; and on the admissibility of evidence. He/she shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence.

(11) **Rights of Parties**: During a hearing, each of the parties shall have the right, subject to the presiding officer's rulings, to:

(a) Call and examine witnesses;

(b) Introduce exhibits;

(c) Cross-examine any witness on any matter relevant to the issue;

(d) Impeach any witness;

(e) Rebut any evidence.

If the applicant or Member who requested the hearing does not testify in its own behalf, representatives of the application who are present may be called and examined as if under cross-examination.

(12) **Procedure and Evidence**: The hearing need not be conducted strictly according to rules of law relating to the examination of witnesses or presentation of evidence. Any relevant matter upon which responsible persons customarily rely in the conduct of serious affairs shall be admitted, regardless of the admissibility of such evidence in a court of law. Each party shall, prior to or during the hearing, be entitled to submit memoranda concerning any issue, and such memoranda shall become part of the hearing record. The presiding officer may, but shall not be required to, order that oral evidence be taken only on oath or affirmation administered by any person designated by him/her and entitled to notarize documents in the state where the hearing is held.

(13) **Official Notice**: In reaching a decision, the hearing committee may take official notice, either before or after submission of the matter for decision, of any generally accepted technical or scientific matter relating to the issues under consideration and of any facts that may be judicially noticed by the courts of the state where the hearing is held. Parties present at the hearing shall be informed of the matters to be thus noticed and those matters shall be noted in the hearing record. Any party shall be given opportunity, on timely request, to request that a matter be officially noticed and to refute the officially noticed matters by evidence or by written or oral presentation of authority, the manner of such refutation to be determined by the hearing committee. The committee shall also be entitled to consider all other information that can be considered, pursuant

to these Bylaws, in connection with applications for membership, applications for designation as a transplant program, or requests for corrective action.

(14) **Burden of Proof**: The body whose adverse recommendation or action occasioned the hearing shall have the initial obligation to present evidence in support thereof, including an explanation of the action or recommendation and why it was taken. The applicant or Member who requested the hearing shall then have the burden of proving and persuading, by clear and convincing evidence, that the adverse recommendation or action lacks any substantial factual basis or that such basis or the conclusions drawn therefrom are arbitrary, unreasonable, or capricious.

(15) **Record of Hearing**: A record of the hearing shall be kept that is of sufficient accuracy to permit an informed and valid judgment to be made by any group that may later be called upon to review the record and render an appellate recommendation or decision in the matter. The hearing committee and the applicant or Member shall, by mutual agreement, select the method to be used for making the record such as court reporter, electronic recording unit, detailed transcription, or minutes of the proceedings. In the absence of mutual agreement, a court reporter shall be in attendance and shall prepare a written transcript. All exhibits admitted into evidence at the hearing and all memoranda submitted to the hearing committee before, during, or after the hearing, shall be incorporated in the record.

(16) **Postponement**: Request for postponement of a hearing shall be granted by the hearing committee only upon a showing of good cause and only if the request therefor is made as soon as is reasonably practicable.

(17) **Presence of Hearing Committee Members and Vote**: A majority of the hearing committee must be present throughout the hearing and deliberations. If a committee member is absent from any part of the proceedings, he/she shall not be permitted to participate in the committee's deliberations or the decision.

(18) **Recesses and Adjournment**: The hearing committee may recess the hearing and reconvene the same without additional notice for the convenience of the participants or for the purpose of obtaining new or additional evidence or consultation. Upon conclusion of the presentation of oral and written evidence, the hearing shall be closed. The hearing committee shall thereupon, at a time convenient to itself, conduct its deliberations outside the presence of the parties. Upon conclusion of its deliberations, the hearing shall be declared finally adjourned.

(19) **Hearing Committee Report**: Following preparation of the hearing record, the hearing committee shall make a written report of its findings and recommendations in the matter and shall forward the same, together with the hearing record and all other documentation considered by it, to the body whose adverse recommendation or action occasioned the hearing. At the same time, a copy of the hearing committee report shall be forwarded to the applicant or Member. All findings and recommendations by the hearing committee shall be supported by reference to the hearing record. The presiding officer may extend the time for making the hearing committee's written report in his/her discretion by giving written notice to the participants.

(20) **Action on Hearing Committee Report**: Following receipt of the report of the hearing committee, the MPSC, MPSC subcommittee, the Executive Committee, or the Board of Directors, as the case may be, shall consider the same and affirm, modify, or reverse its recommendation or action in the matter. It shall transmit a concise statement of the result and the reasons therefor, together with the hearing record, the report of the hearing committee, and all other documentation considered, to the Executive Director.

(21) **Notice**: The Executive Director, or his/her designee, shall promptly send a copy of the result to the applicant or Member by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication, or registered or certified mail, return receipt requested) ~~registered or certified mail, return receipt requested~~. A

copy of the result also shall be forwarded to the MPSC, Executive Committee, and/or to the Board of Directors in the event the applicant or Member exercises its rights to appellate review under Section 3.03A of the Bylaws. The applicant or Member may request that a copy of the hearing record and related documentation be furnished at the applicant's or Member's expense.

(22) **Effect of Favorable Result**:

(a) **Adopted by the Board of Directors or Executive Committee**: If the Board of Directors' or Executive Committee's action is favorable to the applicant or Member, such action shall become the final decision of the Board and the matter shall be considered finally closed.

(b) **Adopted by the MPSC**: If the MPSC's action is favorable to the applicant or Member, the Executive Director shall promptly forward it, together with all supporting documentation, to the Board of Directors for its final action. The Board shall take action thereon by adopting or rejecting the MPSC's action in whole or in part, or by referring the matter back to the MPSC for further consideration. Any such referral back shall state the reasons therefor, set a limit within which a subsequent recommendation to the Board must be made, and may include a directive that an additional hearing be conducted to clarify issues that are in doubt. After receipt of such subsequent recommendation and any new evidence in the matter, the Board shall take final action. The Executive Director shall promptly send the applicant or Member notice by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication, or registered or certified mail, return receipt requested) ~~registered or certified mail, return receipt requested~~, informing him/her of each action taken. Favorable action shall become the final decision of the Board of Directors, and the matter shall be considered finally closed. In the case of favorable action with respect to a Category I potential violation that has resulted in notice to the Secretary of HHS and/or public, the Board of Directors shall remove the designation of Member Not in Good Standing or probation, as applicable, with appropriate notice thereof, and recommend restoration of unrestricted membership privileges to the Secretary of HHS. If the Board's action is adverse, the special notice shall inform the applicant or Member of his right to request an appellate review by the Board of Directors as provided in Section 3.03A below, unless the Board itself has conducted the hearing.

(23) **Effect of Adverse Result**: If the result of the MPSC or of the Board of Directors or the Executive Committee continues to be adverse to the applicant or Member, the notice sent to him by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication, or registered or certified mail, return receipt requested)~~registered or certified mail, return receipt requested~~, shall inform him of any applicable right to request an appellate review by the Board of Directors as provided in section 3.03A below.

3.03A - Appellate Review

(1) **Request for Appellate Review**:

(a) Except in the case of Category I potential violations, in which the Board of Directors has not been the forum for the Member's exercise of hearing rights, an applicant or Member shall have 14 days following his receipt of notice that a hearing resulted in adverse action to file a written request for appellate review. Such request shall be delivered to the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) ~~certified or registered mail~~ and may include a request for a copy of the report and record of the hearing committee and all other material, favorable or unfavorable, if not previously forwarded, that was considered in making the adverse action or result. The applicant or Member may be represented during the appellate

review by an attorney. If the applicant or Member wishes to be so represented, the request for appellate review shall include a statement to that effect and identify by name and business address the attorney who will represent the applicant or Member. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of OPTN requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the Member has not had the opportunity for an appellate review.

(b) **Category I Potential Violations**. In the case of Category I potential violations in which the Board of Directors has not been the forum for the Member's exercise of hearing rights, a Member shall have seven days following his receipt of notice that a hearing resulted in adverse action to file a written request for appellate review. Such request shall be delivered to the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) ~~certified or registered mail~~ and may include a request for a copy of the report and record of the hearing committee and all other material, favorable or unfavorable, if not previously forwarded, that was considered in making the adverse action or result. If the Board of Directors is the forum for the exercise of the Member's procedural rights, there is no right to Appellate Review and the decision of the Board is final. The Member may be represented during the appellate review by an attorney. If the Member wishes to be so represented, the request for appellate review shall include a statement to that effect and identify by name and business address the attorney who will represent the Member. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of OPTN requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the steps for a Category I proceeding have not been completed or the Member otherwise has not had the opportunity for an appellate review.

(2) **Waiver by Failure to Request Appellate Review**: An applicant or Member who fails to request an appellate review within the time and manner specified in section 3.03A(1) above waives any right to such review.

(3) **Notice of Time and Place for Appellate Review**:

(a) Upon receipt of a timely request for appellate review, the Executive Director shall deliver such request to the Board of Directors. As soon as practicable, the Board shall schedule and arrange for an appellate review which, except in the case of Category I potential violations, shall be not less than 30 days from the date of receipt of the appellate review request. At least 25 days prior to the appellate review, the Executive Director shall send the applicant or Member notice of the time, place, and date of the review by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication, or registered or certified mail, return receipt requested)~~registered or certified mail, return receipt requested~~. The time for the appellate review may be extended by the appellate review body for good cause and if the request therefor is made as soon as is reasonably practicable.

(b) **Category I Potential Violations**. In the case of Category I potential violations, the Board shall schedule and arrange for an appellate review not less than seven nor more than 30 days from the date of receipt of the appellate review request. At least five days prior to the appellate review, the Executive Director shall send the applicant or Member notice of the time, place, and date of the review by facsimile or electronic transmission. The time for the appellate review may be extended by the appellate review body for good cause and if the request therefor is made as soon as is reasonably practicable.

(4) **Appellate Review Body**: The appellate review shall be conducted by the Board as a whole.

(5) **Nature of Proceedings**: The proceedings by the review body shall be in the nature of an appellate review based upon the record of the hearing before the hearing committee, that committee's report, and all subsequent results and actions thereon. The appellate review body shall also consider any written or oral statements submitted by the applicant or Member, and its representative(s), if any, and any written or oral statements by the MPSC or the Board of Directors and any of their members, individually.

(6) **Written Statements**: The applicant or Member seeking the review may submit a written statement detailing the findings of fact, conclusions, and procedural matters with which it disagrees, and the reasons for such disagreement. This written statement may cover any matters raised at any step in the hearing process, and legal counsel may assist in its preparation. The statement shall be submitted to the appellate review body through the Executive Director or his/her designee at least 15 days prior to the scheduled date of the appellate review, except if such time limit is waived or modified by the appellate review body. A written statement in reply may be submitted by the MPSC or by the Board of Directors, and if submitted, the Executive Director, or his/her designee, shall provide a copy thereof to the applicant or Member at least 5 days prior to the scheduled date of the appellate review or such shorter time as determined by the appellate review body.

(7) **Presiding Officer**: The chair of the appellate review body shall be the presiding officer. He/she shall determine the order of procedure during the review, make all required rulings, and maintain decorum.

(8) **Oral Statement**: The appellate review body, in its sole discretion, may allow the parties or their representatives to personally appear and make oral statements in favor of their positions. Any party or representative so appearing shall be required to answer questions put to him/her by any member of the appellate review body.

(9) **Consideration of New or Additional Matters**: An applicant or Member may introduce at the appellate review matters or evidence related to steps taken after the conclusion of the original hearing to bring the applicant or Member into full compliance with membership qualifications or requirements. Other new or additional matters or evidence not raised or presented during the original hearing or in the hearing report and not otherwise reflected in the record shall be introduced at the appellate review only in the discretion of the appellate review body, following an explanation by the party requesting the consideration of such matter or evidence as to why it was not presented earlier. In the discretion of the appellate review body, new or additional matters or evidence permitted to be introduced at the appellate review may, but need not, be referred back to the hearing committee in accordance with section 3.03A(13) below.

(10) **Powers**: The appellate review body shall have all the powers granted to the hearing committee, and such additional powers as are reasonably appropriate to the discharge of its responsibilities.

(11) **Presence of Members and Vote**: A majority of the appellate review body must be present throughout the review and deliberations. If a member of the review body is absent from any part of the proceedings, he/she shall not be permitted to participate in the deliberations or the decision.

(12) **Recesses and Adjournment**: The appellate review body may recess the review proceedings and reconvene the same without additional notice for the convenience of the participants or for the purpose of obtaining new or additional evidence or consultation. Upon the conclusion of oral statements, if allowed, the appellate review shall be closed. The appellate review body shall thereupon, at a time convenient to itself, conduct its deliberations outside the presence of the parties. Upon the conclusions of those deliberations, the appellate review shall be declared finally adjourned.

(13) **Action Taken**: The appellate review body may recommend affirmation, modification, or reversal the adverse result or action taken by the MPSC, by the Executive Committee or by a committee of

the Board or, in its discretion, may refer the matter back to the hearing committee for further review and recommendation to be returned to it in accordance with its instructions. After receipt of such recommendations after referral, the appellate review body shall make its decision as provided in this section. In the case of favorable action, which reverses an adverse result with respect to a Category I potential violation that has resulted in notice to the Secretary of HHS and/or public, the Board of Directors shall remove the designation of Member Not in Good Standing or probation, as applicable, with appropriate notice thereof, and recommend restoration of unrestricted membership privileges to the Secretary of HHS.

(14) **Conclusion**: The appellate review shall not be deemed to be concluded until all of the procedural steps provided herein have been completed or waived.

Final Decision of the Board of Directors

4.01A - Board of Directors Action

After the MPSC forwards a recommendation to the Board of Directors for which an applicant or Member waives the hearing and appellate review rights or after the conclusion of hearing and appellate review proceedings, the Board shall render its final decision in the matter (which, in the case of an appellate review proceeding, shall be the decision of the Appellate Review Body) in writing and shall send notice thereof to the applicant or Member by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) ~~certified or registered mail~~, and to the Secretary of HHS within three business days or such longer period as may be necessitated for good cause, as determined by the Secretary, if the decision continues to be adverse to the applicant or Member. A majority vote by a quorum is required for the Board to take any action permitted by these Bylaws.

If the Board should decide that a more serious sanction than the sanction recommended by the MPSC or Executive Committee is appropriate, the Board shall return the matter to the MPSC or Executive Committee, as the case may be, for its consideration of the imposition of the more serious sanction. If the MPSC or Executive Committee agrees with the Board, the more serious sanction shall be the final decision of the Board. If the MPSC or Executive Committee does not agree that the more serious sanction is appropriate, its initial recommendation to the Board shall be the final decision of the Board.

Notice of a final decision by the Board of Directors or Executive Committee that the Member has been placed on probation or declared Not in Good Standing shall be circulated to all Members. The membership shall be notified of final decisions by the Board or Executive Committee to recommend to the Secretary of HHS suspension of membership privileges or termination of membership only upon approval of such recommendations by the Secretary.

Costs and Expenses

6.03A - Default in Payment of Reimbursable Cost and Expenses

Any applicant or Member who fails to pay reimbursable costs and expenses assessed pursuant to Section 6.01A within 30 days after having received notice by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) ~~certified or registered mail~~, at the applicant or Member's address as shown on the records of the OPTN Contractor, shall be referred to the Secretary for termination of either OPTN membership or further consideration of the application, as appropriate.

II. Transplant Hospitals

A. General [No changes]
B. Survival Rates [No changes]

C. Functional Inactivity, Inactive Transplant Program Status, Relinquishment of Designated Transplant Program Status and Termination of Designated Transplant Program Status.

For the purposes of these bylaws, a candidate is defined as an individual who has been added to the waiting list. A potential candidate is defined as an individual who is under evaluation for transplant by the transplant program. Each reference to a candidate includes potential candidates if and as applicable.

1. Functional Inactivity. Transplant programs must remain functionally active. Transplant program functional activity will be reviewed periodically by the Membership and Professional Standards Committee (MPSC).

For purposes of these Bylaws, "Functional Inactivity" is defined as any or all of the items below:

(a) The inability to serve potential candidates, candidates, or recipients, for a period of 15 days or more consecutively;
(b) failure to perform a transplant during the following stated periods of time:

i. In the case of kidney, liver, and heart transplant programs, within three consecutive months;

ii. In the case of pancreas and lung programs, within six consecutive months;

iii. In the case of stand-alone pediatric transplant hospitals, within twelve consecutive months.

(c) waiting list inactivation of 15 or more consecutive days and/or 28 cumulative days or more over any 365 consecutive day period.

(d) given their experimental and evolving nature, functional inactivity thresholds and waiting list notification requirements regarding functional inactivity have not been established for pancreatic islet and intestinal transplant programs.

Any program identified to be functionally inactive shall be provided the opportunity to explain its inactivity through reports requested by the MPSC.

A transplant program must provide written notice to candidates when the transplant program:

(a) Inactivates its waiting list or is unable to perform transplants for 15 consecutive days or more;

(b) Inactivates its waiting list or is unable to perform transplants for 28 cumulative days or more over any 365 consecutive day period;

The MPSC may also require, at its discretion, that the Member participate in an informal discussion regarding a performance review. The informal discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.

A functionally inactive transplant program should voluntarily inactivate for a period of up to twelve months by providing written notice to the Executive Director. If the transplant program expects to be inactive for more than twelve months, the Member should relinquish designated transplant program status for the program in accordance with these bylaws.

The MPSC may recommend that a program inactivate or relinquish its designated transplant program status due to the program's functional inactivity. If the program fails to inactivate or relinquish its designated transplant status upon the MPSC's recommendation to do so, the MPSC may recommend the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws. Potential adverse actions are defined under Section 3.01A of the bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the situation.

2. Inactive Transplant Program Status. For the purposes of these bylaws, inactive transplant program status is defined as:

- an inactive transplant program waiting list status in UNetSM (short-term inactivation), or
- an inactive transplant program waiting list status in UNetSM and an inactive
- membership status (long-term inactivation).

A Member may voluntarily inactivate a transplant program, on a short-term or long-term basis, for reasons including but not limited to:

- inability to meet functional activity requirements;
- temporarily lacking required physician and/or surgeon coverage;
- substantial change in operations that require temporary cessation of transplantation.

a. Short-Term Inactivation

Short-term inactivation means that a transplant program may be inactive for up to 14 consecutive days. A Member may voluntarily inactivate a transplant program for a period not to exceed 14 days by changing the program's waiting list status in UNet^{SM}.

i. **Notice to the OPTN Contractor.** When a Member intends to voluntarily inactivate a transplant program on a short-term basis, the Member is not required to notify the OPTN contractor.

ii. **Notice to Patients.** In accordance with Attachment I to Appendix B, Section VII each transplant program must provide potential candidates, candidates, and recipients with a written summary of its Program Coverage Plan at the time of listing or when there are any substantial changes in program or personnel.

b ~~a~~. Long-Term Inactivation

Long-term inactivation means inactivation of a transplant program for 15 or more days consecutively. Members should voluntarily inactivate programs that are not able to serve potential candidates, candidates, or recipients, for a period of 15 or more days consecutively. Voluntary inactivation may extend for a period of up to 12 months.

i. Notice to the OPTN Contractor. When a Member intends to voluntarily inactivate a transplant program for 15 or more days consecutively, it must provide written notice, including the reason(s) for inactivation, to the OPTN Executive Director upon deciding to inactivate the transplant program.

ii. Notice to the Patients. When a Member intends to inactivate a transplant program for 15 or more days consecutively, it must provide:

a) written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently being followed by the transplant program. Written notice should be provided ~~mailed~~ at least 30 days prior to the anticipated inactivation date by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication, or registered or certified mail, return receipt requested) ~~certified mail/return receipt requested~~. Written notice must be provided ~~mailed~~ no later than seven days following inactivation and include:

1) the reason(s) for inactivating the transplant program;
2) notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
3) options for potential candidates, candidates, recipients, and living donors to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, recipient, and living donor transfers.

The Member must provide a representative copy of the patient notice to the OPTN contractor along with a list of potential candidates, candidates, recipients, and living donors who received the notice.

In the event of a natural disaster that adversely affects a transplant program, the patient notification requirements shall be applied reasonably and flexibly.

3. Transition Plan. When the Member inactivates a transplant program for 15 or more days consecutively, it must:

a) promptly suspend organ implantation for that transplant program;
b) assist potential candidates and candidates in identifying designated transplant programs to which they can transfer;

c) provide a list to the OPTN contractor of all of the transplant program's candidates at the time of inactivation and update it throughout this process;

d) indicate on the list provided the decision of each potential candidate and each candidate to transfer, with the following additional information:

   i) if a candidate or potential candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision; or

   ii) if a candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic updates will be required as to the status of each candidate's transfer progress until the candidate is evaluated by the accepting program and an official decision is made regarding the candidate's listing status.

e) expedite removal of all candidates from the inactive transplant program's waiting list, or, if the candidate requests, transfer the candidate to another OPTN Member transplant hospital;

f) initiate transfer of all active candidates or potential candidates hospitalized at the inactive transplant program to an accepting transplant hospital within seven days of inactivation of the transplant program. The inactive transplant program must complete the transfer process within 14 days unless transfer would be unsafe or discharge is anticipated within that time; or circumstances outside of the program's control exist that prevent transfer within 14 days. The program must document and submit to the OPTN contractor all efforts for transfer of its hospitalized candidates or potential candidates if it is unable to meet the time periods within this section.

g) provide a priority list of the most urgent candidates or potential candidates at the inactive transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:

   i) for liver candidates, all Status 1A and 1B candidates must be transferred within seven days of program inactivation, followed by all active candidates in descending MELD/PELD score order, with all candidates whose MELD/PELD score exceeds 25 to be transferred within 30 days, followed by all inactive candidates;

   ii) for lung candidates, active candidates should be transferred according to descending Lung Allocation Scores followed by inactive candidates;

   iii) for kidney candidates, those whose PRA(measured or calculated) is over 80% should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;

   iv) for heart candidates, all Status 1A and 1B must be transferred within seven days of inactivation;

   v) for multi-visceral organ transplant candidates, transfer must be completed within 30 days of inactivation; and

   vi) notwithstanding these guidelines, all active candidates who choose to transfer should be transferred within 60 days of inactivation.

   vii) The program must document and submit to the OPTN contractor all efforts for transfer of its candidates if it is unable to meet the time periods within this section.

h) document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates; and

i) remove every transplant candidate from the inactive transplant program's waiting list within 12 months of the program's inactivation date in the cases when a program does not intend to reactivate.

Transplant programs that inactivate for 15 or more days consecutively may still have the ability to provide care to transplant candidates, recipients and living donors. Should the transplant program continue to provide follow-up care to transplant recipients and living donors, the program must continue to submit OPTN follow-up forms via UNet[SM]. Alternatively, transplant recipients may transfer care to another institution.

4. **Extension of Voluntary Inactive Program Status Beyond Twelve Months**. A Member transplant hospital may request an extension of voluntary inactive program status beyond twelve months by making a request to the MPSC. The request must demonstrate to the MPSC's satisfaction the benefit of such an extension, and be accompanied by a comprehensive plan with a timeline for re-starting transplantation at the program. This demonstration must include assurance that all membership criteria will be met at the time of re-starting transplantation.

5. **Reactivation after Voluntary Long Term Inactivation**. A Member transplant hospital may reactivate its program after long term voluntary inactivation by submitting application materials deemed appropriate by the MPSC that establishes that the program has again become active in organ transplantation and that all criteria for membership are met. The Membership and Professional Standards Committee shall recommend to the Board of Directors that the Board so notify the Secretary of HHS.

6. **Relinquishment or Termination of Designated Transplant Program Status.** Relinquishment of Designated Transplant Program Status means that a Member may voluntarily give up its designated transplant program status upon written notice to the OPTN. Members that relinquish designated transplant program status are voluntarily closing the transplant program.

Termination of Designated Transplant Program Status means that a Member's designated program status is terminated by the Secretary of the Department of Health and Human Services ("Secretary"). In the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors and/or the Executive Committee request approval from the Secretary to terminate a Member's designated transplant program status in accordance with Appendix A Section 2.06A of these Bylaws. The Board of Directors and/or the Executive Committee may, on its own accord, request such approval from the Secretary.

Once a Member relinquishes a designated transplant program status or it is terminated by the Secretary of HHS, that transplant program may no longer perform organ transplants. The Member must facilitate the transfer of the subject transplant program's candidates to another transplant program.

a. **Notice to the OPTN Contractor.** A Member transplant hospital must provide written notice to the OPTN contractor within 30 days of the intent to relinquish its designated transplant program status and the reasons therefor upon deciding to relinquish designated transplant program status.

b. **Notice to the Patients.** When a Member transplant hospital intends to relinquish its designated transplant program status, or its designated transplant program status is terminated, it must provide:

i) written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently being followed by the transplant program. Written notice should be provided ~~mailed~~ at least 30 days prior to the anticipated date of relinquishment or termination by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure

electronic communication, or registered or certified mail, return receipt requested) ~~certified mail/return receipt requested~~. Written notice must be provided ~~mailed~~ no later than seven days following relinquishment/termination and include:

1. the reason(s) for loss of designated transplant program status;
2. notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
3. options for potential candidates, candidates, recipients, and living donors to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, and recipient transfers; and

The Member transplant hospital must provide a representative copy of the patient notice to the OPTN contractor along with a list of potential candidate, candidate, and recipient names who received the notice.

c. **Transition Plan.** When a Member transplant hospital relinquishes a transplant program's designated program status or its designated program status is terminated, it must:

i. promptly suspend organ implantation for the transplant program;

ii. assist potential candidates and candidates in identifying designated transplant programs to which they can transfer;

iii. provide a list to the OPTN contractor of all of the transplant program's candidates on the waiting list at the time of relinquishment or termination and update it throughout this process;

iv. indicate on the list provided the decision of each potential candidate and each candidate to transfer, with the following additional information:

1. if a candidate or potential candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision; or
2. if a candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic updates will be required as to the status of each candidate's transfer progress until the candidate is evaluated by the accepting program and an official decision is made regarding the candidate's listing status.

v. expedite removal of all candidates from the transplant program's waiting list, or, if the patient requests, transfer the candidate to another OPTN Member transplant hospital;

vi. initiate transfer of all active candidates hospitalized at the transplant program to an accepting transplant hospital within seven days of relinquishment of the transplant program. The transplant program must complete the transfer process within 14 days unless transfer would be unsafe or discharge is anticipated within that time; or circumstances outside of the program's control exist that prevent transfer within 14 days. The program must document and submit to the OPTN contractor all efforts to transfer its hospitalized candidates if it is unable to meet the time periods within this section.

vii. provide a priority list of the most urgent candidates listed at the transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:

1. for liver candidates, all Status 1A and 1B candidates must be transferred within seven days of relinquishment, followed by all active candidates in descending MELD/PELD score order, with all candidates whose MELD/PELD score exceeds 25 to be transferred within 30 days, followed by all inactive candidates;
2. for lung candidates, active candidates should be transferred according to descending Lung Allocation Scores with highest scores first, followed by inactive candidates;
3. for kidney candidates, those whose PRA (measured or calculated) is over 80% should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;
4. for heart candidates, all Status 1A and 1B must be transferred within seven days of relinquishment;
5. for multi-visceral organ transplant candidates, transfer must be completed within 30 days of relinquishment; and
6. notwithstanding these guidelines, all active candidates should be transferred within 60 days of relinquishment; and;
7. The program must document and submit to the OPTN contractor all efforts for transfer of its candidates if it is unable to meet the time periods within this section.

viii. document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates; and

ix. remove every transplant candidate from the transplant program's waiting list within 12 months of the program's relinquishment date.

A Member that relinquishes or terminates a designated transplant program may still have the ability to temporarily provide care to transplant candidates and provide follow-up care to transplant recipients and living donors. Should the transplant program continue to provide follow-up care to transplant recipients and living donors, the program must continue to submit OPTN follow up forms via UNetSM. Alternatively, transplant recipients may transfer care to another institution.

6. **Waiting time on waiting list**. To assure equity in waiting times, and facilitate smooth transfer of candidates from the waiting list affected programs (i.e. programs that voluntarily inactivate, relinquish or lose designated transplant program status), candidates on the waiting list in such instances may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of the programs' inactivation, relinquishment, or loss of designated status. This total acquired waiting time will be transferred to the candidate's credit when s(he) is listed with a new program.

7. **Laboratory Tests**. The inactivated program remains responsible for evaluating its candidates. This includes, but is not limited to performing laboratory tests and evaluations required to maintain the candidate's appropriate status on the waiting list until the time of transfer.

D – K [No further changes to this section]

1.11 Removal of Non-Qualifying Members.

a. Transplant center Institutional Members that fail to qualify as a UNOS Member under Article 1.2(b) shall be treated in accordance with Article II of Appendix B to these Bylaws.

b. All other UNOS Members who cease to qualify for UNOS membership under Article I of these Bylaws may be removed as UNOS Members in accordance with the following procedures:

1. The Member may request removal from UNOS membership by forwarding a written request therefor to UNOS, or

2. Even if the Member does not request removal, UNOS may notify the Member in writing that, unless the Member demonstrates that it continues to meet applicable membership criteria within sixty (60) days of notification, the Member's UNOS membership will be terminated.

i. If, within sixty (60) days of such notification, the Member demonstrates, to the satisfaction of UNOS, that the Member continues to meet UNOS membership requirements, UNOS shall withdraw its notice of termination.

ii. If the Member fails to demonstrate that it continues to meet applicable UNOS membership requirements, its membership in UNOS will terminate on the sixtieth (60th) day after notification of termination by UNOS. The Member can appeal this decision to the Board of Directors. In the event a Member exercises this right of appeal, the Member shall notify UNOS of this exercise by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested) ~~registered or certified mail, return receipt requested~~. Pending a decision on the appeal, the process defined by these procedures shall continue unless the Board directs otherwise. In the event the appeal is denied, the process shall be further continued or reinitiated, as applicable. Any other decision on the appeal by the Board shall be submitted to the Membership and Professional Standards Committee as appropriate for action consistent with the Board's decision.

c. Any Member that requests removal from UNOS membership or is otherwise removed from UNOS membership under this Article 1.11 may later re-apply for membership in accordance with Article 1.7 of these Bylaws.

1.12 Meetings. The annual meeting of the Members to elect a Board of Directors pursuant to Article 2.1 of these Bylaws, to elect Principal Officers pursuant to Section 6.1 of these Bylaws and to address such other matters as may be appropriate shall be held in February or March of each calendar year and may be held in conjunction with the annual meeting of the Board of Directors. Special meetings of the Members may be called at any time by the President, Executive Director, or a majority of the Board of Directors, or by written application of a majority of the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Member Electors, Public Organization Member Electors, Medical/Scientific Member Electors, and Individual Member Electors stating the time, place, and purpose of the meeting. Members attending meetings shall do so at no cost to UNOS. Meetings of the UNOS membership typically shall be open to the public; however, discussions involving confidential matters including, UNOS member admission, credentialing, monitoring, or disciplinary matters and matters involving individuals' privacy where disclosure would constitute a clearly unwarranted invasion of personal privacy, shall be reserved for closed sessions as appropriate and consistent with the OPTN Contract.

Written notice of any regular or special meeting of the Members shall state the date, time, and place of the meeting and the purpose for which the meeting is called, and shall be provided ~~mailed~~ to each Member not fewer than 25 or more than 60 days before the date of the meeting. Giving notice of a meeting of Members to a Member or Member Elector who is not eligible to vote does not imply that the Member or Member Elector may vote.

A written waiver of notice signed at any time by a Member or Member Elector shall be the equivalent of any notice required herein. A Member or Member Elector who attends a meeting shall be deemed to have had timely and proper notice of the meeting unless the Member or Member Elector attends for the express purpose of objecting that the meeting is not lawfully called or convened.

Article II
Board of Directors

2.6 **Notice of Meetings**. Written notice of any regular or special meeting of the Board of Directors shall state the place, date and time of the meeting and shall be provided ~~mailed~~ to each Director at the address on file with the Executive Director not fewer than 10 or more than 60 days before the date of the meeting. The Executive Director shall circulate the agenda for each Board of Directors meeting to the Members at least 10 days prior to the meeting in order to promote input from the Members to the Directors. A written waiver of notice signed by a Director, whether before or after the time stated therein, shall be the equivalent of the giving of any notice required herein. A Director who attends a meeting shall be deemed to have had timely and proper notice thereof.

Article X
Amendment of the Bylaws

10.2 **Notice**. Notice of any meeting at which an amendment to the By-Laws is proposed shall be provided ~~sent by mail~~ to each Director at the address on file with the Executive Director no fewer than 10 nor more than 60 days before the date of the meeting, accompanied by a copy of the proposed amendment.

Appendix A to Bylaws
United Network for Organ Sharing
Corrective Action and Enforcement of UNOS Requirements
OPO, Transplant Hospital, and Histocompatibility Laboratory Members

2.04A Requests

All requests for corrective action to enforce membership requirements shall be submitted to the MPSC in writing by the Executive Director or his/her designee, and shall be supported by reference to the specific activities or conduct which constitute the grounds for the request. The Executive Director, or his/her designee, shall promptly give notice of such request for corrective action to the Member by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested) ~~registered or certified mail, return receipt requested~~.

2.11A Procedural Rights

Procedural rights, including "interviews and hearings," are further described in Section 3.01A – 3.03A of the Bylaws. If the member does not deliver a written request for an interview to the Chairperson of the MPSC or the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail)~~certified or registered mail~~ within 14 days following his receipt of such notice, the Member waives its rights to an interview and the MPSC may proceed to implement its proposed action.

Appendix A to Bylaws
United Network for Organ Sharing
Interviews and Hearings

3.01A **Definition of "Adverse"**

(1) **Recommendations or Actions**: Subject to Section 3.01A(4) below, the following recommendations or actions shall, if deemed adverse pursuant to Section 3.01A(2) below, entitle the applicant or member affected thereby to a hearing:

(a) Rejection of initial membership or rejection of designation as a transplant program;

(b) Probation;

(c) Initial declaration of "Member Not in Good Standing" and subsequent determinations by the Board of Directors or Executive Committee not to restore the Member to unrestricted membership status;

(d) Suspension of membership privileges either directly or after a period of probation;

(e) Termination of membership, either directly or after a period of probation or suspension; and

(f) Any other action specified in Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c) including, by way of example and not limitation, removal of designation as a transplant program.

(2) **When Deemed Adverse:** A recommendation or action listed in Section 3.01A(1) above shall be deemed adverse only when it has been:

(a) Recommended by the MPSC or, in the case of: (i) rejection of initial membership, (ii) rejection of designation as a transplant program, or (iii) findings with respect to Category I potential violations, recommended by a Subcommittee of the MPSC; or

(b) Taken by the Board of Directors or the Executive Committee contrary to a favorable recommendation by the MPSC or subcommittee of the MPSC under circumstances where no right to a hearing existed; or

(c) Taken by the Board of Directors or the Executive Committee on its own initiative without benefit of a prior recommendation by the MPSC.

(3) **Interviews:** Except in the case of Category I potential violations, when the MPSC or MPSCPCSC is considering making an adverse recommendation concerning an applicant or a Member or issuing a letter of reprimand, or when an organ-specific committee refers a matter to the MPSC/MPSC-PCSC with a recommendation that the MPSC consider such an action under Section 2.05A above, the applicant or Member shall be entitled to an interview before the MPSC or the MPSC-PCSC. The interview shall not constitute a hearing, shall be preliminary in nature, and shall not be conducted according to the procedural rules provided with respect to hearings. The applicant or Member shall be informed of the general nature of the circumstances and may present information relevant thereto. A summary record of such interview shall promptly be made by the MPSC and a copy promptly provided to the applicant or Member who was granted the interview. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of UNOS requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the

Member has not had the opportunity for an interview and/or other procedural rights described below.

Members shall not be entitled to an interview in the case of Category I potential violations; or if action is being considered pursuant to 5.05A or 5.07A of these Bylaws.

(a) An applicant or Member shall have the right to one hearing proceeding, and subsequent appellate review unless the Board of Directors conducts the hearing, with respect to any application for membership, application for designation as a transplant program, and request for corrective action to enforce membership requirements in which an adverse recommendation or action is taken. The hearing may be requested upon the first to occur of the adverse recommendations or actions listed in section 3.01A(1) above or, if waived at such time by the applicant's or member's failure to request a hearing within the time and in the manner specified in section 3.02A below, upon any subsequent adverse recommendation or action arising out of the same application for membership, application for designation as a transplant program, or request for corrective action to enforce membership requirements.

(b) **Category I Potential Violations.** In the case of a determination of time sensitive threat to patient health or public safety in connection with Category I potential violations, the hearing and any subsequent appellate review will commence together with or follow rather than precede the Executive Committee's or the Board's decision regarding and action upon the MPSC subcommittee's recommendation, as set forth below:

(i) The MPSC subcommittee recommendation will be referred immediately to the Executive Committee. At the same time, notice will be given to the Member by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested)~~registered or certified mail, return receipt requested~~., as well as facsimile transmission. Where the finding continues to be a Category I potential violation with time sensitive threat to patient health or public safety, the MPSC subcommittee action shall include a recommendation for designation of the Member to be Member Not in Good Standing and that the offending transplant program or institution voluntarily inactivate, and, failing acceptance of this recommendation to voluntarily inactivate with immediate action to so inactivate (including notice to and assistance for patients pursuant to UNOS requirements);

(ii) Following receipt of the MPSC subcommittee recommendation, the Executive Committee shall determine whether it or the Board of Directors shall consider the matter and the Executive Committee or the Board, as the case may be, shall consider the same and affirm, modify, or reverse the recommendation or action in the matter. A concise statement of the result and the reasons therefore, and all documentation considered, shall be transmitted to the Executive Director;

(iii) The Executive Director, or his/her designee, shall promptly send a copy of the result to the Member by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested)~~registered or certified mail, return receipt requested~~. (as well as facsimile transmission) if the decision continues to be adverse to the Member. A copy of the result also shall be forwarded to the MPSC or to the Board of Directors, as determined by the Executive Committee, in the event the Member exercises its rights to a hearing under Section 3.02A of the Bylaws. The Member may request that a copy of the supporting documentation be furnished at the Member's expense;

(iv) Notice of a decision by the Executive Committee or Board that the Member has been placed on probation or declared Not in Good Standing shall be circulated to all Members; and

(v) In the event the Member exercises its right to a hearing, the process described in Section 3.02A will be initiated or continued, as applicable, consistent with the timing of delivery and receipt of notices. The hearing will be before the MPSC, the Board or the Executive Committee as determined by the Executive Committee.

Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of UNOS requirements poses a substantial and imminent threat to the quality of patient care, the Board may take other appropriate action using other appropriate process even if the steps noted above for a Category I proceeding have not been completed or the Member otherwise has not had the opportunity for a hearing and/or subsequent appellate review.

Members will not be entitled to a Hearing in the case that action is being considered pursuant to 5.05A or 5.07A of these Bylaws, except as provided in those sections.

(4) **Right to a Hearing:** An applicant or Member shall have the right to one hearing proceeding, and subsequent appellate review, with respect to any application for membership application for designation as a transplant program, or request for corrective action to enforce membership requirements in which an adverse recommendation or action is taken. The hearing may be requested upon the first to occur of the adverse recommendations or actions listed on Section 3.01A(1) above or, if waived at such time by the applicant's or member's failure to request a hearing within the time and in the manner specified in Section 3.03A below, upon any subsequent adverse recommendation or action arising out of the same application for membership, application for designation as a transplant program, or request for corrective action to enforce membership requirements. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of UNOS requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the Member has not had the opportunity for a hearing and/or subsequent appellate review.

3.02A Hearings

(1) **Parties:** The parties to a hearing shall be the applicant or Member against whom an adverse recommendation or action has been taken and the MPSC, the Executive Committee, or the Board of Directors, i.e., the body whose adverse recommendation or action is at issue.

(2) **Notice of Adverse Recommendation or Action:** An applicant or Member against whom an adverse recommendation or action has been taken shall promptly be given notice of such action by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested)~~registered or certified mail, return receipt requested~~. Such notice shall:

(a) Briefly advise the applicant or Member of the nature of the adverse recommendation or action and the grounds therefor;
(b) Advise the applicant or Member of the right to a hearing pursuant to the provisions of these Bylaws;
(c) Specify the number of days following the date of receipt of notice within which a request for a hearing must be submitted;
(d) State that the failure to request a hearing within the specified time period shall constitute a waiver of rights to a hearing and to any appellate review of the matter;

(e) State that all materials about the applicant or Member that were generated by or submitted to the MPSC, the Executive Committee or the Board, as the case may be, prior to that body's adverse recommendation or action, shall be made available to the applicant or Member, upon request, for inspection and copying; and

(f) State that upon UNOS' receipt of the hearing request, the applicant or Member will be notified of the date, time and place of the hearing.

(3) **Request for Hearing:**

(a) Except in the case of Category I potential violations, an applicant or member shall have 14 days following his receipt of a notice to file a written request for a hearing. If the applicant or Member wishes to be represented at the hearing by an attorney, the request for hearing shall include a statement to that effect and identify by name and business address the attorney who will represent the applicant or Member. Such requests shall be delivered to the Chair of the MPSC or the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail)~~certified or registered mail~~; and

(b) **Category I Potential Violations.** In the case of Category I potential violations, an applicant or Member shall have seven days following his receipt of a notice to file a written request for a hearing. If the applicant or Member wishes to be represented at the hearing by an attorney, the request for hearing shall include a statement to that effect and identify by name and business address the attorney who will represent the applicant or Member. Such requests shall be delivered to the chair of the MPSC or the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail)~~certified or registered mail~~.

(4) **Waiver by Failure to Request a Hearing:** An applicant or Member who fails to request a hearing within the time and in the manner specified waives any right to such a hearing or any appellate review to which he might otherwise have been entitled. Such waiver in connection with:

(a) An adverse action by the Board of Directors or Executive Committee shall constitute acceptance of that action, which shall thereupon become effective as the final decision by the Board; and

(b) An adverse recommendation by the MPSC or Executive Committee shall constitute acceptance of that recommendation, which shall thereupon become and remain effective pending the final decision of the Board of Directors.

(5) **Notice of Hearing:** Upon receipt of a timely request for a hearing, notification of the time, place, and date of the hearing shall be sent to the applicant or Member by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail)~~certified mail~~ at least 7 days prior to the hearing.

(6) **Statement of Issues:** The notice of hearing described in Section 3.02A(5) above shall contain a concise statement of the issues raised by the adverse recommendation or action which is the subject of the hearing.

(7) **Appointment of Hearing Committees:**

(a) **By MPSC:** A hearing occasioned by an adverse MPSC recommendation shall be conducted by a Hearing Committee appointed by the Chair of the MPSC and composed of three (3) members of the MPSC or in the discretion of the Chair, shall be composed of those MPSC members who are in attendance at a regular or special MPSC meeting and are not disqualified under Section 3.02A(8) below;

(b) **By Board of Directors:** A hearing occasioned by an adverse action of the Board of Directors may be conducted by a Hearing Committee appointed by the Chair of the Board of Directors and composed of three (3) Directors. One of the appointees shall be designated as Chair. Alternatively, in the discretion of the chair of the Board, the hearing shall be conducted by those Board Members who are in attendance at a regular or special meeting of the Board, provided that such Members are not disqualified under Section 3.02A(8) below and constitute at least a quorum of the full Board; and

(c) **By MPSC-PCSC or Ad Hoc MPSC Subcommittee/Executive Committee or Board in the Case of Category I Potential Violations:** A hearing occasioned by an adverse recommendation from a subcommittee of the MPSC or Executive Committee or Board in the case of Category I potential violations shall be conducted by a hearing committee appointed by the chair and composed of at least three (3) members of the MPSC or, in the discretion of the chair, shall be composed of those members who are in attendance at a regular or special meeting and are not disqualified under section 3.02A(8) below, provided that such members constitute at least a quorum of the full committee or Board.

(8) **Service on Hearing Committee:** A MPSC or Board of Directors member shall be disqualified from serving on a Hearing Committee if he/she has been personally and directly involved in compiling evidence for UNOS on the matter at issue.

(9) **Appearance and Representation:** Appearance by the applicant or Member who requested the hearing shall be required. An applicant or Member who fails without good cause to appear and proceed at such hearing shall be deemed to have waived his rights to such a hearing or any appellate review to which it might otherwise have been entitled. The applicant or Member may be represented by an attorney at any hearing or at any appellate review proceeding. The MPSC, MPSC subcommittee, Executive Committee, or the Board of Directors shall be allowed representation by an attorney.

(10) **Presiding Officer:** The Chair of the Hearing Committee shall be the Presiding Officer. The Presiding Officer shall regulate the course of the hearing to assure that all participants in the hearing have a reasonable opportunity to present relevant oral and documentary evidence and to conduct such cross-examination as may be required for a full and true disclosure of the facts. He/she shall determine the order of procedure during the hearing and shall make all rulings on interpretation or construction of UNOS' Articles of Incorporation, Bylaws and other relevant document and UNOS requirements on procedure; and on the admissibility of evidence. He/she shall provide for the exclusion of irrelevant, immaterial or unduly repetitious evidence.

(11) **Rights of Parties:** During a hearing, each of the parties shall have the right, subject to the Presiding Officer's rulings, to:

(a) Call and examine witnesses;

(b) Introduce exhibits;

(c) Cross-examine any witness on any matter relevant to the issue;

(d) Impeach any witness; and

(e) Rebut any evidence.

If the applicant or member who requested the hearing does not testify in its own behalf, representatives of the application who are present may be called and examined as if under cross-examination.

(12) **Procedure and Evidence**: The hearing need not be conducted strictly according to rules of law relating to the examination of witnesses or presentation of evidence. Any relevant matter upon which responsible persons customarily rely in the conduct of serious affairs shall be admitted, regardless of the admissibility of such evidence in a court of law. Each party shall, prior to or during the hearing, be entitled to submit memoranda concerning any issue, and such memoranda shall become part of the hearing record. The Presiding Officer may, but shall not be required to, order that oral evidence be taken only on oath or affirmation administered by any person designated by him and entitled to notarize documents in the state where the hearing is held.

(13) **Official Notice:** In reaching a decision, the Hearing Committee may take official notice, either before or after submission of the matter for decision, of any generally accepted technical or scientific matter relating to the issues under consideration and of any facts that may be judicially noticed by the courts of the state where the hearing is held. Parties present at the hearing shall be informed of the matters to be thus noticed and those matters shall be noted in the hearing record. Any party shall be given opportunity, on timely request, to request that a matter be officially noticed and to refute the officially noticed matters by evidence or by written or oral presentation of authority, the manner of such refutation to be determined by the Hearing Committee. The committee shall also be entitled to consider all other information that can be considered, pursuant to these Bylaws, in connection with applications for membership, applications for designation as a transplant program, or requests for corrective action.

(14) **Burden of Proof**: The body whose adverse recommendation or action occasioned the hearing shall have the initial obligation to present evidence in support thereof, including an explanation of the action or recommendation and why it was taken. The applicant or Member who requested the hearing shall then have the burden of proving and persuading, by clear and convincing evidence, that the adverse recommendation or action lacks any substantial factual basis or that such basis or the conclusions drawn therefrom are either arbitrary, unreasonable, or capricious.

(15) **Record of Hearing:** A record of the hearing shall be kept that is of sufficient accuracy to permit an informed and valid judgment to be made by any group that may later be called upon to review the record and render an appellate recommendation or decision in the matter. The Hearing Committee and the applicant or Member shall, by mutual agreement, select the method to be used for making the record such as court reporter, electronic recording unit, detailed transcription, or minutes of the proceedings. In the absence of mutual agreement, a court reporter shall be in attendance and shall prepare a written transcript. All exhibits admitted into evidence at the hearing and all memoranda submitted to the Hearing Committee before, during or after the hearing, shall be incorporated in the record.

(16) **Postponement**: Request for postponement of a hearing shall be granted by the Hearing Committee only upon a showing of good cause and only if the request therefor is made as soon as is reasonably practicable.

(17) **Presence of Hearing Committee Members and Vote**: A majority of the Hearing Committee must be present throughout the hearing and deliberations. If a Committee member is absent from any part of the proceedings, he shall not be permitted to participate in the Committee's deliberations or the decision.

(18) **Recesses and Adjournment**: The Hearing Committee may recess the hearing and reconvene the same without additional notice for the convenience of the participants or for the purpose of obtaining new or additional evidence or consultation. Upon conclusion of the presentation of oral and written evidence, the hearing shall be closed. The Hearing Committee shall thereupon, at a time convenient to itself, conduct its deliberations outside the presence of the parties. Upon conclusion of its deliberations, the hearing shall be declared finally adjourned.

(19) **Hearing Committee Report**: Following preparation of the hearing record, the Hearing Committee shall make a written report of its findings and recommendations in the matter and shall

forward the same, together with the hearing record and all other documentation considered by it, to the body whose adverse recommendation or action occasioned the hearing. At the same time, a copy of the Hearing Committee Report shall be forwarded to the applicant or member. All findings and recommendations by the Hearing Committee shall be supported by reference to the hearing record. The Presiding Officer may extend the time for making the Hearing Committee's written report in his/her discretion by giving written notice to the participants.

(20) **Action on Hearing Committee Report:** Following receipt of the report of the Hearing Committee, the MPSC, MPSC subcommittee, the Executive Committee, or the Board of Directors, as the case may be, shall consider the same and affirm, modify or reverse its recommendation or action in the matter. It shall transmit a concise statement of the result and the reasons therefor, together with the hearing record, the report of the Hearing Committee and all other documentation considered, to the Executive Director.

(21) **Notice**: The Executive Director, or his/her designee, shall promptly send a copy of the result to the applicant or Member by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested)~~registered or certified mail, return receipt requested~~. A copy of the result also shall be forwarded to the MPSC, Executive Committee and/or to the Board of Directors in the event the applicant or Member exercises its rights to appellate review under Section 3.03A of the Bylaws. The applicant or Member may request that a copy of the hearing record and related documentation, be furnished at the applicant's or Member's expense.

(22) **Effect of Favorable Result:**

(a) **Adopted by the Board of Directors or Executive Committee**: If the Board of Directors' or Executive Committee's action is favorable to the applicant or Member, such action shall become the final decision of the Board and the matter shall be considered finally closed.

(b) **Adopted by the MPSC:** If the MPSC's action is favorable to the applicant or Member, the Executive Director shall promptly forward it, together with all supporting documentation, to the Board of Directors for its final action. The Board shall take action thereon by adopting or rejecting the MPSC's action in whole or in part, or by referring the matter back to the MPSC for further consideration. Any such referral back shall state the reasons therefor, set a limit within which a subsequent recommendation to the Board must be made, and may include a directive that an additional hearing be conducted to clarify issues that are in doubt. After receipt of such subsequent recommendation and any new evidence in the matter, the Board shall take final action. The Executive Director shall promptly send the applicant or Member notice by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested)~~registered or certified mail, return receipt requested~~, informing him of each action taken. Favorable action shall become the final decision of the Board of Directors, and the matter shall be considered finally closed. In the case of favorable action with respect to a Category I potential violation that the Board of Directors shall remove the designation of Member Not in Good Standing or probation, as applicable, with appropriate notice, thereof. If the Board's action is adverse, the special notice shall inform the applicant or member of his right to request an appellate review by the Board of Directors as provided in Section 3.03A below, unless the Board itself has conducted the hearing.

(23) **Effect of Adverse Result:** If the result of the MPSC or of the Board of Directors or the Executive Committee continues to be adverse to the applicant or member, the notice sent to him by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt

requested)~~registered or certified mail, return receipt requested~~, shall inform him of any applicable right to request an appellate review by the Board of Directors as provided in Section 3.03A below.

3.03A Appellate Review

(1) **Request for Appellate Review:**

(a) Except in the case of Category I potential violations, in which the Board of Directors has not been the forum for the Member's exercise of hearing rights, an applicant or Member shall have 14 days following his receipt of notice that a hearing resulted in adverse action to file a written request for appellate review. Such request shall be delivered to the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail)~~certified or registered mail~~ and may include a request for a copy of the report and record of the Hearing Committee and all other material, favorable or unfavorable, if not previously forwarded, that was considered in making the adverse action or result. The applicant or Member may be represented during the appellate review by an attorney. If the applicant or Member wishes to be so represented, the request for appellate review shall include a statement to that effect and identify by name and business address the attorney who will represent the applicant or Member. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of UNOS requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the Member has not had the opportunity for an appellate review; and

(b) **Category I Potential Violations.** In the case of Category I potential violations in which the Board of Directors has not been the forum for the Member's exercise of hearing rights, a Member shall have seven days following his receipt of notice that a hearing resulted in adverse action to file a written request for appellate review. Such request shall be delivered to the Executive Director either in person or by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) ~~certified or registered mail~~ and may include a request for a copy of the report and record of the hearing committee and all other material, favorable or unfavorable, if not previously forwarded, that was considered in making the adverse action or result. If the Board of Directors is the forum for the exercise of the Member's procedural rights, there is no right to Appellate Review and the decision of the Board is final. The Member may be represented during the appellate review by an attorney. If the Member wishes to be so represented, the request for appellate review shall include a statement to that effect and identify by name and business address the attorney who will represent the Member. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of UNOS requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the steps for a Category I proceeding have not been completed or the Member otherwise has not had the opportunity for an appellate review.

(2) **Waiver by Failure to Request Appellate Review:** An applicant or Member who fails to request an appellate review within the time and manner specified in Section 3.03A(1) above waives any right to such review.

(3) **Notice of Time and Place for Appellate Review:**

(a) Upon receipt of a timely request for appellate review, the Executive Director shall deliver such request to the Board of Directors. As soon as practicable, the Board shall schedule and arrange for an appellate review, which, except in the case of Category I potential violations, shall be not less than 30 days from the date of receipt of the appellate review

request. At least 25 days prior to the appellate review, the Executive Director shall send the applicant or Member notice of the time, place and date of the review by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail, return receipt requested) ~~registered or certified mail, return receipt requested~~. The time for the appellate review may be extended by the Appellate Review Body for good cause and if the request therefor is made as soon as is reasonably practicable; and

(b) **Category I Potential Violations**. In the case of Category I potential violations, the Board shall schedule and arrange for an appellate review not less than seven nor more than 30 days from the date of receipt of the appellate review request. At least five days prior to the appellate review, the Executive Director shall send the applicant or Member notice of the time, place, and date of the review by facsimile or electronic transmission. The time for the appellate review may be extended by the appellate review body for good cause and if the request therefor is made as soon as is reasonably practicable.

(4) **Appellate Review Body**: The appellate review shall be conducted by the Board as a whole.

(5) **Nature of Proceedings:** The proceedings by the review body shall be in the nature of an appellate review based upon the record of the hearing before the Hearing Committee, that committee's report, and all subsequent results and actions thereon. The Appellate Review Body shall also consider any written or oral statements submitted by the applicant or Member, and its representative(s), if any, and any written or oral statements by the MPSC or the Board of Directors and any of their members, individually.

(6) **Written Statements:** The applicant or Member seeking the review may submit a written statement detailing the findings of fact, conclusions and procedural matters with which it disagrees, and the reasons for such disagreement. This written statement may cover any matters raised at any step in the hearing process, and legal counsel may assist in its preparation. The statement shall be submitted to the Appellate Review Body through the Executive Director or his/her designee at least 15 days prior to the scheduled date of the appellate review, except if such time limit is waived or modified by the Appellate Review Body. A written statement in reply may be submitted by the MPSC or by the Board of Directors, and if submitted, the Executive Director or his/her designee, shall provide a copy thereof to the applicant or Member at least 5 days prior to the scheduled date of the appellate review or such shorter time as determined by the appellate review body.

(7) **Presiding Officer:** The Chair of the Appellate Review Body shall be the Presiding Officer. He/she shall determine the order of procedure during the review, make all required rulings, and maintain decorum.

(8) **Oral Statement:** The Appellate Review Body, in its sole discretion, may allow the parties or their representatives to personally appear and make oral statements in favor of their positions. Any party or representative so appearing shall be required to answer questions put to him/her by any member of the Appellate Review Body.

(9) **Consideration of New or Additional Matters:** An applicant or Member may introduce at the appellate review matters or evidence related to steps taken after the conclusion of the original hearing to bring the applicant or Member into full compliance with membership qualifications or requirements. Other new or additional matters or evidence not raised or presented during the original hearing or in the hearing report and not otherwise reflected in the record shall be introduced at the appellate review only in the discretion of the Appellate Review Body, following an explanation by the party requesting the consideration of such matter or evidence as to why it was not presented earlier. In the discretion of the Appellate Review Body, new or additional matters or evidence permitted to be introduced at the appellate review may, but need not, be referred back to the Hearing Committee in accordance with Section 3.03A(13) below.

(10) **Powers:** The Appellate Review Body shall have all the powers granted to the Hearing Committee, and such additional powers as are reasonably appropriate to the discharge of its responsibilities.

(11) **Presence of Members and Vote:** A majority of the Appellate Review Body must be present throughout the review and deliberations. If a member of the Review Body is absent from any part of the proceedings, he/she shall not be permitted to participate in the deliberations or the decision.

(12) **Recesses and Adjournment:** The Appellate Review Body may recess the review proceedings and reconvene the same without additional notice for the convenience of the participants or for the purpose of obtaining new or additional evidence or consultation. Upon the conclusion of oral statements, if allowed, the appellate review shall be closed. The Appellate Review Body shall thereupon, at a time convenient to itself, conduct its deliberations outside the presence of the parties. Upon the conclusions of those deliberations, the appellate review shall be declared finally adjourned.

(13) **Action Taken**: The appellate review body may recommend affirmation, modification, or reversal the adverse result or action taken by the MPSC, by the Executive Committee or by a committee of the Board or, in its discretion, may refer the matter back to the hearing committee for further review and recommendation to be returned to it in accordance with its instructions. After receipt of such recommendations after referral, the appellate review body shall make its decision as provided in this section. In the case of favorable action, which reverses an adverse result with respect to a Category I potential violation that has resulted in notice to the public, the Board of Directors shall remove the designation of Member Not in Good Standing or probation, as applicable, with appropriate notice thereof, and restoration of unrestricted membership privileges.

(14) **Conclusion:** The appellate review shall not be deemed to be concluded until all of the procedural steps provided herein have been completed or waived.

Appendix A to Bylaws
United Network for Organ Sharing
Final Decision of Board of Directors

4.01A Board of Directors Action

After the MPSC forwards a recommendation to the Board of Directors for which an applicant or Member waives the hearing and appellate review rights or after the conclusion of hearing and appellate review proceedings, the Board shall render its final decision in the matter (which, in the case of an appellate review proceeding, shall be the decision of the Appellate Review Body) in writing and shall send notice thereof to the applicant or Member by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail)~~certified or registered mail~~. A majority vote by a quorum is required for the Board to take any action permitted by these Bylaws. If the Board should decide that a more serious sanction than the sanction recommended by the MPSC or Executive Committee is appropriate, the Board shall return the matter to the MPSC or Executive Committee, as the case may be, for its consideration of the imposition of the more serious sanction. If the MPSC or Executive Committee agrees with the Board, the more serious sanction shall be the final decision of the Board. If the MPSC or Executive Committee does not agree that the more serious sanction is appropriate, its initial recommendation to the Board shall be the final decision of the Board. Notice of a final decision by the Board of Directors or Executive Committee that the Member has been placed on probation or declared Not in Good Standing shall be circulated to all Members.

Appendix A to Bylaws
United Network for Organ Sharing
Costs and Expenses

6.03A - Default in Payment of Reimbursable Cost and Expenses

Any applicant or Member who fails to pay reimbursable costs and expenses assessed pursuant to Section 6.01A within 30 days after having received notice by a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) ~~certified or registered mail~~, at the applicant or Member's address as shown on the records of UNOS, shall be referred for termination of either UNOS membership or further consideration of the application, as appropriate.

APPENDIX B TO BYLAWS
UNITED NETWORK FOR ORGAN SHARING

II. Transplant Hospitals

C. Functional Inactivity, Inactive Transplant Program Status, Relinquishment of Designated Transplant Program Status and Termination of Designated Transplant Program Status.
For the purposes of these bylaws, a candidate is defined as an individual who has been added to the waiting list. A potential candidate is defined as an individual who is under evaluation for transplant by the transplant program. Each reference to a candidate includes potential candidates if and as applicable.

1. Functional Inactivity. Transplant programs must remain functionally active. Transplant program functional activity will be reviewed periodically by the Membership and Professional Standards Committee (MPSC).

For purposes of these Bylaws, "Functional Inactivity" is defined as any or all of the items below:

(a) The inability to serve potential candidates, candidates, or recipients, for a period of 15 days or more consecutively;

(b) failure to perform a transplant during the following stated periods of time:

i. In the case of kidney, liver, and heart transplant programs, within three consecutive months;

ii. In the case of pancreas and lung programs, within six consecutive months;

iii. In the case of stand-alone pediatric transplant hospitals, within twelve consecutive months.

(c) waiting list inactivation of 15 or more consecutive days and/or 28 cumulative days or more over any 365 consecutive day period.

(d) given their experimental and evolving nature, functional inactivity thresholds and waiting list notification requirements regarding functional inactivity have not been established for pancreatic islet and

Any programs identified to be functionally inactive shall be provided the opportunity to explain its inactivity through reports requested by the MPSC.

A transplant program must provide written notice to candidates when the transplant program:

(a) Inactivates its waiting list or is unable to perform transplants for 15 consecutive days or more;

(b) Inactivates its waiting list or is unable to perform transplants for 28 cumulative days or more over any 365 consecutive day period;

The MPSC may also require, at its discretion, that the Member participate in an informal discussion regarding a performance review. The informal discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.

A functionally inactive transplant program should voluntarily inactivate for a period of up to twelve months by providing written notice to the Executive Director. If the transplant program expects to be inactive for more than twelve months, the Member should relinquish designated transplant program status for the program in accordance with these bylaws.

The MPSC may recommend that a program inactivate or relinquish its designated transplant program status due to the program's functional inactivity. If the program fails to inactivate or relinquish its designated transplant status upon the MPSC's recommendation to do so, the MPSC may recommend the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws. Potential adverse actions are defined under Section 3.01A of the bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the situation.

2. Inactive Transplant Program Status. For the purposes of these bylaws, inactive transplant program status is defined as:

- an inactive transplant program waiting list status in UNetSM (short-term inactivation), or
- an inactive transplant program waiting list status in UNetSM and an inactive membership status (long-term inactivation).

A Member may voluntarily inactivate a transplant program, on a short-term or long-term basis, for reasons including but not limited to:

- inability to meet functional activity requirements;
- temporarily lacking required physician and/or surgeon coverage;
- substantial change in operations that require temporary cessation of transplantation.

a. Short-Term Inactivation

Short-term inactivation means that a transplant program may be inactive for up to 14 consecutive days. A Member may voluntarily inactivate a transplant program for a period not to exceed 14 days by changing the program's waiting list status in UNetSM.

i. **Notice to UNOS.** When a Member intends to voluntarily inactivate a transplant program on a short-term basis, the Member is not required to notify the UNOS.

ii. **Notice to Patients.** In accordance with Attachment I to Appendix B, Section VII transplant program must provide potential candidates, candidates, and recipients with a written summary of its Program Coverage Plan at the time of listing or when there are any substantial changes in program or personnel.

b. Long-Term Inactivation

Long-term inactivation means inactivation of a transplant program for 15 or more days consecutively. Members should voluntarily inactivate programs that are not able to serve potential candidates, candidates, or recipients, for a period of 15 or more days. Voluntary inactivation may extend for a period of up to 12 months.

i. **Notice to UNOS.** When a Member intends to voluntarily inactivate a transplant program for 15 or more days consecutively, it must provide written notice, including the reason(s) for inactivation, to the UNOS Executive Director upon deciding to inactivate the transplant program.

ii. **Notice to the Patients.** When a Member intends to inactivate a transplant program for 15 or more days consecutively, it must provide:

a) written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently being followed by the transplant program. Written notice should be provided ~~mailed~~ at least 30 days prior to the anticipated inactivation date by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication, or registered or certified mail, return receipt requested) ~~certified mail/return receipt requested~~. Written notice must be provided ~~mailed~~ no later than seven days following inactivation and include:

1) the reason(s) for inactivating the transplant program;
2) notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
3) options for potential candidates, candidates, recipients, and living donors to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, recipient, and living donor transfers.

The Member must provide a representative copy of the patient notice to UNOS along with a list of potential candidates, candidates, recipients, and living donors who received the notice.

In the event of a natural disaster that adversely affects a transplant program, the patient notification requirements shall be applied reasonably and flexibly.

3. **Transition Plan.** When the Member inactivates a transplant program for 15 or more days consecutively, it must:

a) promptly suspend organ implantation for that transplant program;

b) assist potential candidates and candidates in identifying designated transplant programs to which they can transfer;

c) provide a list to UNOS of all of the transplant program's candidates at the time of inactivation and update it throughout this process;

d) indicate on the list provided the decision of each potential candidate and each candidate to transfer, with the following additional information:

i) if a candidate or potential candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision; or

ii) if a candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic updates will be required as to the status of each candidate's transfer progress until the candidate is evaluated by the accepting program and an official decision is made regarding the candidate's listing status.

e) expedite removal of all candidates from the inactive transplant program's waiting list, or, if the candidate requests, transfer the candidate to another UNOS Member transplant hospital;

f) initiate transfer of all active candidates or potential candidates hospitalized at the inactive transplant program to an accepting transplant hospital within seven days of inactivation of the transplant program. The inactive transplant program must complete the transfer process within 14 days unless transfer would be unsafe or discharge is anticipated within that time; or circumstances outside of the program's control exist that prevent transfer within 14 days. The program must document and submit to UNOS all efforts for transfer of its hospitalized candidates or potential candidates if it is unable to meet the time periods within this section.

g) provide a priority list of the most urgent candidates or potential candidates at the inactive transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:

i) for liver candidates, all Status 1A and 1B candidates must be transferred within seven days of program inactivation, followed by all active candidates in descending MELD/PELD score order, with all candidates whose MELD/PELD score exceeds 25 to be transferred within 30 days, followed by all inactive candidates;

ii) for lung candidates, active candidates should be transferred according to descending Lung Allocation Scores followed by inactive candidates;

iii) for kidney candidates, those whose PRA(measured or calculated) is over 80% should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;

iv) for heart candidates, all Status 1A and 1B must be transferred within seven days of inactivation;

v) for multi-visceral organ transplant candidates, transfer must be completed within 30 days of inactivation; and

vi) notwithstanding these guidelines, all active candidates who choose to transfer should be transferred within 60 days of inactivation.

vii) The program must document and submit to UNOS all efforts for transfer of its candidates if it is unable to meet the time periods within this section.

h) document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates; and

i) remove every transplant candidate from the inactive transplant program's waiting list within 12 months of the program's inactivation date in the cases when a program does not intend to reactivate.

Transplant programs that inactivate for 15 or more days consecutively may still have the ability to provide care to transplant candidates, recipients and living donors. Should the transplant program continue to provide follow-up care to transplant recipients and living donors, the program must continue to submit OPTN follow-up forms via UNetSM. Alternatively, transplant recipients may transfer care to another institution.

4. **Extension of Voluntary Inactive Program Status Beyond Twelve Months**. A Member transplant hospital may request an extension of voluntary inactive program status beyond twelve months by making a request to the MPSC. The request must demonstrate to the MPSC's satisfaction the benefit of such an extension, and be accompanied by a comprehensive plan with a timeline for re-starting transplantation at the program. This demonstration must include assurance that all membership criteria will be met at the time of re-starting transplantation.

5. **Reactivation After Voluntary Long Term Inactivation**. A Member transplant hospital may reactivate its program after long term voluntary inactivation by submitting application materials deemed appropriate by the MPSC that establishes that the program has again become active in organ transplantation and that all criteria for membership are met. The Membership and Professional Standards Committee shall recommend to the Board of Directors that the Board so notify the Secretary of HHS.

6. **Relinquishment or Termination of Designated Transplant Program Status:** Relinquishment of Designated Transplant Program Status means that a Member may voluntarily give up its designated transplant program status upon written notice to UNOS. Members that relinquish designated transplant program status are voluntarily closing the transplant program.

Termination of Designated Transplant Program Status means that a Member's designated program status is terminated by the Secretary of the Department of Health and Human Services ("Secretary"). In the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors and/or the Executive Committee request approval from the Secretary to terminate a Member's designated transplant program status in accordance with Appendix A Section 2.06A of these Bylaws. The Board of Directors and/or the Executive Committee may, on its own accord, request such approval from the Secretary.

Once a Member relinquishes a designated transplant program status or it is terminated by the Secretary of HHS, that transplant program may no longer perform organ transplants. The Member must facilitate the transfer of the subject transplant program's candidates to another transplant program.

a. **Notice to the UNOS.** A Member transplant hospital must provide written notice to UNOS within 30 days of the intent to relinquish its designated transplant program status and the reasons therefor upon deciding to relinquish designated transplant program status.

b. **Notice to the Patients.** When a Member transplant hospital intends to relinquish its designated transplant program status, or its designated transplant program status is terminated, it must provide:

i) written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently being followed by the transplant program. Written notice should be provided ~~mailed~~ at least 30 days prior to the anticipated date of relinquishment or termination by a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication, or registered or certified mail, return receipt requested) ~~certified mail/return receipt requested~~. Written notice must be provided ~~mailed~~ no later than seven days following relinquishment/termination and include:

1. the reason(s) for loss of designated transplant program status;
2. notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
3. options for potential candidates, candidates, recipients, and living donors to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, and recipient transfers; and

The Member transplant hospital must provide a representative copy of the patient notice to UNOS along with a list of potential candidate, candidate, and recipient names who received the notice.

c. **Transition Plan.** When a Member transplant hospital relinquishes a transplant program's designated program status or its designated program status is terminated, it must:

i. promptly suspend organ implantation for the transplant program;
ii. assist potential candidates and candidates in identifying designated transplant programs to which they can transfer;
iii. provide a list to UNOS of all of the transplant program's candidates on the waiting list at the time of relinquishment or termination and update it throughout this process;
iv. indicate on the list provided the decision of each potential candidate and each candidate to transfer, with the following additional information:

1. if a candidate or potential candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision; or
2. if a candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic updates will be required as to the status of each candidate's transfer progress until the candidate is evaluated by the accepting program and an official decision is made regarding the candidate's listing status.

v. expedite removal of all candidates from the transplant program's waiting list, or, if the patient requests, transfer the candidate to another UNOS Member transplant hospital;

i. initiate transfer of all active candidates hospitalized at the transplant program to an accepting transplant hospital within seven days of relinquishment of the transplant program. The transplant program must complete the transfer process within 14 days unless transfer would be unsafe or discharge is anticipated within that time; or circumstances outside of the program's control exist that prevent transfer within 14 days. The program must document and submit to UNOS all efforts to transfer its hospitalized candidates if it is unable to meet the time periods within this section.

ii. provide a priority list of the most urgent candidates listed at the transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:

1. for liver candidates, all Status 1A and 1B candidates must be transferred within seven days of relinquishment, followed by all active candidates in descending MELD/PELD score order, with all candidates whose MELD/PELD score exceeds 25 to be transferred within 30 days, followed by all inactive candidates;
2. for lung candidates, active candidates should be transferred according to descending Lung Allocation Scores with highest scores first, followed by inactive candidates;
3. for kidney candidates, those whose PRA (measured or calculated) is over 80% should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;
4. for heart candidates, all Status 1A and 1B must be transferred within seven days of relinquishment;
5. for multivisceral organ transplant candidates, transfer must be completed within 30 days of relinquishment; and
6. notwithstanding these guidelines, all active candidates should be transferred within 60 days of relinquishment; and;
7. The program must document and submit to UNOS all efforts for transfer of its candidates if it is unable to meet the time periods within this section.

i. document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates; and

ii. remove every transplant candidate from the transplant program's waiting list within 12 months of the program's relinquishment date.

A Member that relinquishes or terminates a designated transplant program may still have the ability to temporarily provide care to transplant candidates and provide follow-up care to transplant recipients and living donors. Should the transplant program continue to

provide follow-up care to transplant recipients and living donors, the program must continue to submit OPTN follow up forms via UNetSM. Alternatively, transplant recipients may transfer care to another institution.

6. **Waiting time on waiting list**. To assure equity in waiting times, and facilitate smooth transfer of candidates from the waiting list affected programs (i.e. programs that voluntarily inactivate, relinquish or lose designated transplant program status), candidates on the waiting list in such instances may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of the programs' inactivation, relinquishment, or loss of designated status. This total acquired waiting time will be transferred to the candidate's credit when s(he) is listed with a new program.

7. **Laboratory Tests**. The inactivated program remains responsible for evaluating its candidates. This includes, but is not limited to performing laboratory tests and evaluations required to maintain the candidate's appropriate status on the waiting list until the time of transfer.

Other Considerations:

To be determined